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RE: **Docket No. ATR-2025-0001**

https://www.regulations.gov/comment/ATR-2025-0001-0141

Dear Department of Justice,

For a decade, American insurers blamed diabetics for bankrupting American healthcare. Today we know better. Corporate collusion combined with decades of antitrust inaction by federal agencies have drained healthcare and medical markets of the freedom, ingenuity, and integrity that once made America great. It costs nothing to restore the integrity of the markets. It can only create value, stability, and resilience in the healthcare market, and in the lives of patients, doctors, independent pharmacists, and every American stakeholder.

This paper explores examples of patient experiences with both public and private entities, both governmental and commercial. Patient obstacles are in some cases unintentionally created and, in some cases, intentionally engineered. I leave it to you to determine which experiences might result, either directly or indirectly, from a lack of antitrust enforcement. However, I hold the perspective that the system is already so brittle and prone to failure that America, and particularly patients, cannot continue to accommodate its disability, be it intentionally or unintentionally engineered.

I am indebted to my local community and the EMTs, paramedics, Home Health Aids (HHAs), independent pharmacists, doctors, engineers, fellow diabetics, and members of other patient communities who have helped educate and support me so that I lived long enough to write to the Department of Justice. Please help us.

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Introduction

Minneapolis and Saint Paul, Minnesota make an interesting case study for those interested in healthcare antitrust. The Twin Cities are a geographic hub for the healthcare industry - medical device development, health insurance, and medical practice. It's the location of Medtronic, Abbott Labs, Boston Scientific, United Health Group, and the Mayo Clinic. It is also geographically significant for Type 1 diabetes. Minnesota was the location of settlement for large proportions of Nordic immigrants throughout the 19th century. [1] (Figure 1)

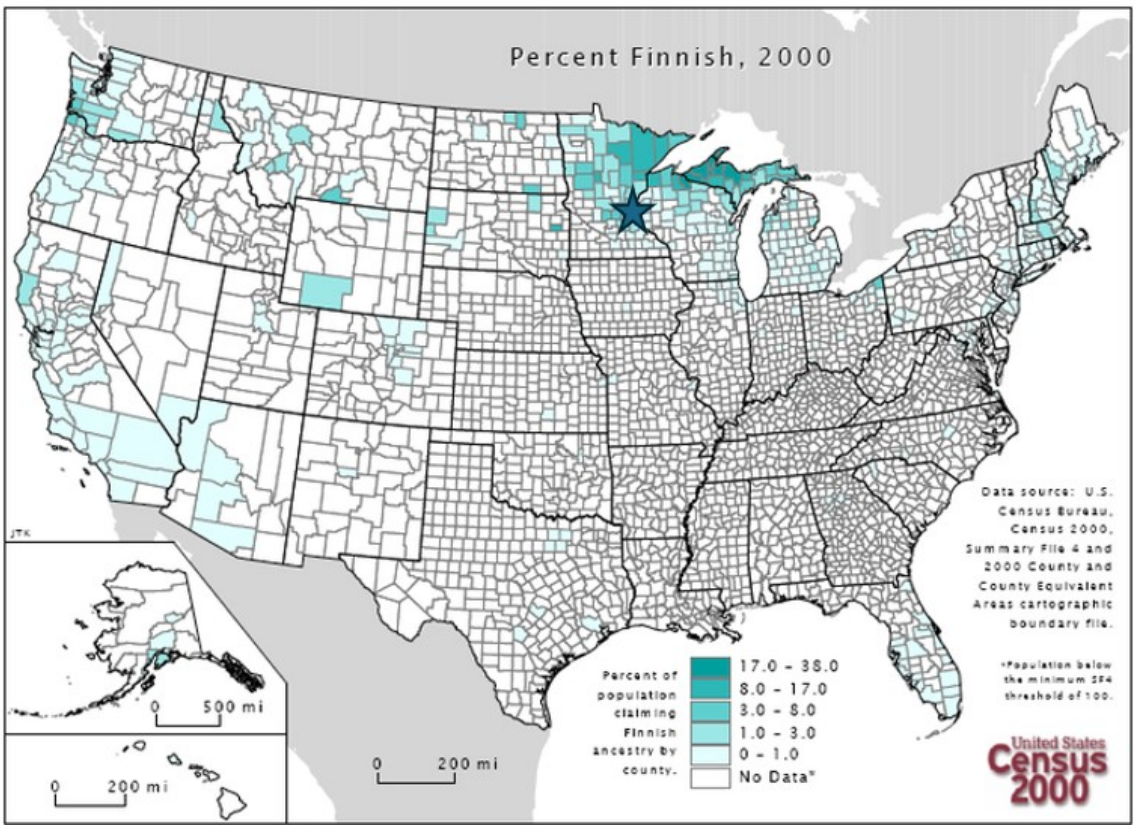

Percent Finnish, 2000
Percent of population claiming Finnish ancestry by county.
17.0 - 38.0
8.0 - 17.0
3.0 - 8.0
1.0 - 3.0
0 - 1.0
No Data*
Data source: U.S. Census Bureau, Census 2000, Summary File 4 and 2000 County and County Equivalent Areas cartographic boundary file.
*Population below the minimum SF4 threshold of 100.
United States Census 2000
0 500 mi
0 200 mi
0 200 mi

***Figure 1**. US Immigration from Finland [1]*

Finland has the highest incidence of type 1 diabetes in the world. [2] (Figure 2) As a result, Nordic companies produce diabetes research and innovation. Novo Nordisk is located in Finland's neighbor, Denmark. It produces medications like Fiasp, Levemir, Novolin, and Ozempic. What types of analogous innovation do we see in the Twin Cities? Are there market forces at play that might result in higher incidence of death for U.S. diabetics than in Finland? (Figure 3) What is the experience of diabetic patients in the healthcare and medical markets? Can we identify innovation in the

marketplace, or is it better characterized as financial and physical coercion based on complex financial instrumentation and market monopolization?

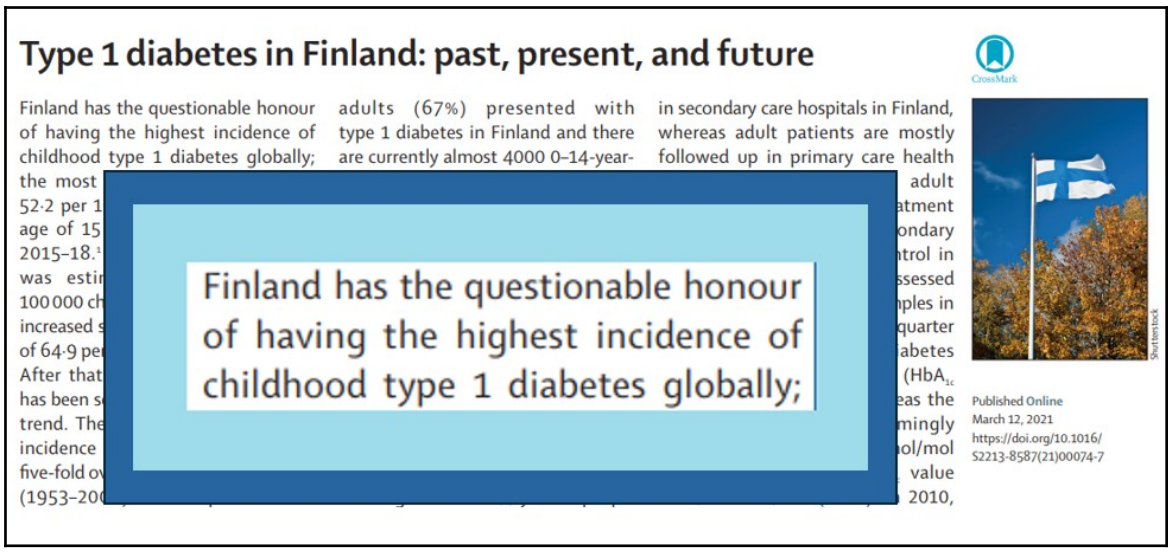

Type 1 diabetes in Finland: past, present, and future
Finland has the questionable honour of having the highest incidence of childhood type 1 diabetes globally;
Published Online
March 12, 2021
https://doi.org/10.1016/
S2213-8587(21)00074-7

***Figure 2**. Incidence of type 1 diabetes in Finland is highest in the world [2]*

	TOTAL DEATHS BY CAUSE PERCENT TOP 50 CAUSES			
	FINLAND		UNITED STATES	
	Deaths	%	Deaths	%
1. Alzheimers & Dementia	11,120	23.00	287,198	11.46
2. Coronary Heart Disease	9,831	20.33	504,904	20.15
3. Stroke	4,115	8.51	158,520	6.33
4. Lung Cancers	2,312	4.78	155,533	6.21
5. Hypertension	2,030	4.20	65,960	2.63
6. Colon-Rectum Cancers	1,433	2.96	61,827	2.47
7. Falls	1,325	2.74	40,418	1.61
8. Lung Disease	1,289	2.67	195,387	7.80
9. Pancreas Cancer	1,247	2.58	44,293	1.77
10. Liver Disease	1,068	2.21	43,402	1.73
11. Prostate Cancer	970	2.01	35,612	1.42
12. Breast Cancer	948	1.96	48,671	1.94
13. Parkinson's Disease	853	1.76	34,491	1.38
14. Lymphomas	851	1.76	40,281	1.61
15. Suicide	846	1.75	53,099	2.12
16. Liver Cancer	545	1.13	27,064	1.08
17. Inflammatory/Heart	518	1.07	32,529	1.30
18. Alcohol	464	0.96	14,659	0.58
19. Stomach Cancer	447	0.92	13,077	0.52
20. Other Injuries	437	0.90	25,997	1.04
21. Influenza and Pneumonia	436	0.90	60,317	2.41
22. Diabetes Mellitus	418	0.86	61,418	2.45

***Figure 3.** Deaths from Diabetes - Finland vs U.S.A.*

Impact of Monopolization on Patient Care

System complexity promotes system failure. That is the fundamental reason that the medical and healthcare system fails for diabetics, and patients more generally. There are no market forces that promote fixing problems in the system. All failures flow downhill onto patients.

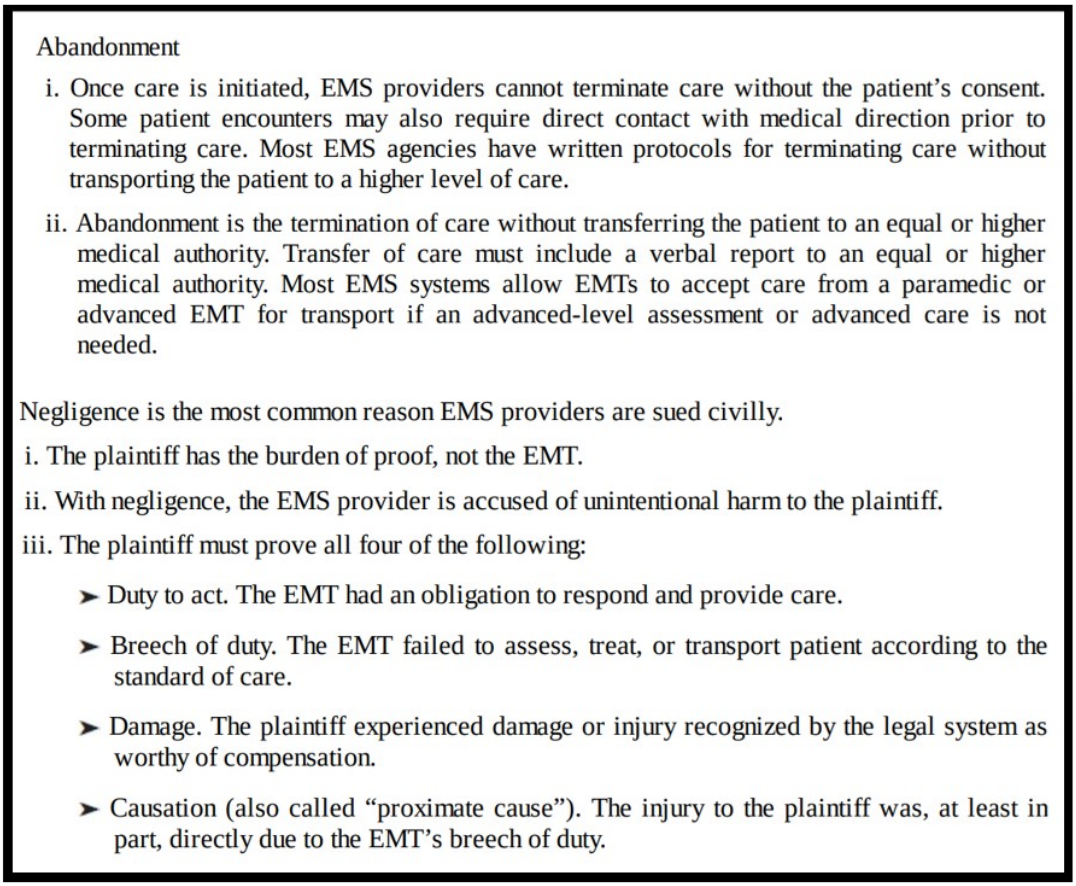
In the best of cases, these failures are unintentional results of system complexity. In the worst cases, failures are the result of health insurers engineering complexity into the system to increase administrative burden and obstacles. I include a recent personal example with each case.

For the purposes of exploration here, I include an evaluation of the following standards of medical care. This is a list of fundamental responsibilities that medical providers, even at the lowest level of authority, are required by law to adhere to: 1.) **Duty to Act**, or the **Duty to Provide Care** up to a standard in accordance with one's individual training/credentials; 2.) Avoid **Patient Abandonment**; and 3.) **Medical Negligence**. (See figure 4) I will assume only the most basic understanding of these concepts, associated with 3 months of medical training and licensure at the level of Emergency Medical Technician (EMT).

Alongside these three provider responsibilities, I include mention of one fundamental patient right – the right to provide **informed consent to treatment**. [17] (Figure 5) As an EMT, I would be required by law to inform every patient of both the risks associated with receiving medical treatment and the risks associated with refusing treatment. If a patient can understand those risks and risks are communicated to them, then they are considered 'legally informed' and deemed capable of providing legal consent to treatment. I will use my experience as a type 1 diabetic and an EMT to evaluate the degree to which these most basic standards of care are practiced and enforced within the medical system today.

Patient care can be complex. However, adherence to medical standards at the lowest level of authority within the medical system can provide basic guidance to assist one in determining if care is being delivered according to basic legal and professional standards in accordance with the Hippocratic Oath and commitments to Do No Harm. When medicine is practiced in a modern context, even software developers find it helpful to fall back on these most fundamental standards. The earliest rewriting of the Hippocratic Oath for a digital context that I encountered was through an organization called I

Am the Calvary from the Las Vegas DEFCON conference of 2013. [29] It demonstrates an understanding that professional ethical and legal standards in medicine are applicable to everyone working in a healthcare context, from young paramedics making $22/hour all the way up to highly paid software security engineers working on medical devices. Exceptions to those foundational principles should not be made. Efforts to interfere with or impede the hands-on practice of medicine should be prosecuted.



Abandonment

i. Once care is initiated, EMS providers cannot terminate care without the patient's consent. Some patient encounters may also require direct contact with medical direction prior to terminating care. Most EMS agencies have written protocols for terminating care without transporting the patient to a higher level of care.

ii. Abandonment is the termination of care without transferring the patient to an equal or higher medical authority. Transfer of care must include a verbal report to an equal or higher medical authority. Most EMS systems allow EMTs to accept care from a paramedic or advanced EMT for transport if an advanced-level assessment or advanced care is not needed.

Negligence is the most common reason EMS providers are sued civilly.

i. The plaintiff has the burden of proof, not the EMT.

ii. With negligence, the EMS provider is accused of unintentional harm to the plaintiff.

iii. The plaintiff must prove all four of the following:

- ➢ Duty to act. The EMT had an obligation to respond and provide care.
- ➢ Breech of duty. The EMT failed to assess, treat, or transport patient according to the standard of care.
- ➢ Damage. The plaintiff experienced damage or injury recognized by the legal system as worthy of compensation.
- ➢ Causation (also called "proximate cause"). The injury to the plaintiff was, at least in part, directly due to the EMT's breech of duty.

Figure 4. *Legal Responsibilities of medical providers [16]*

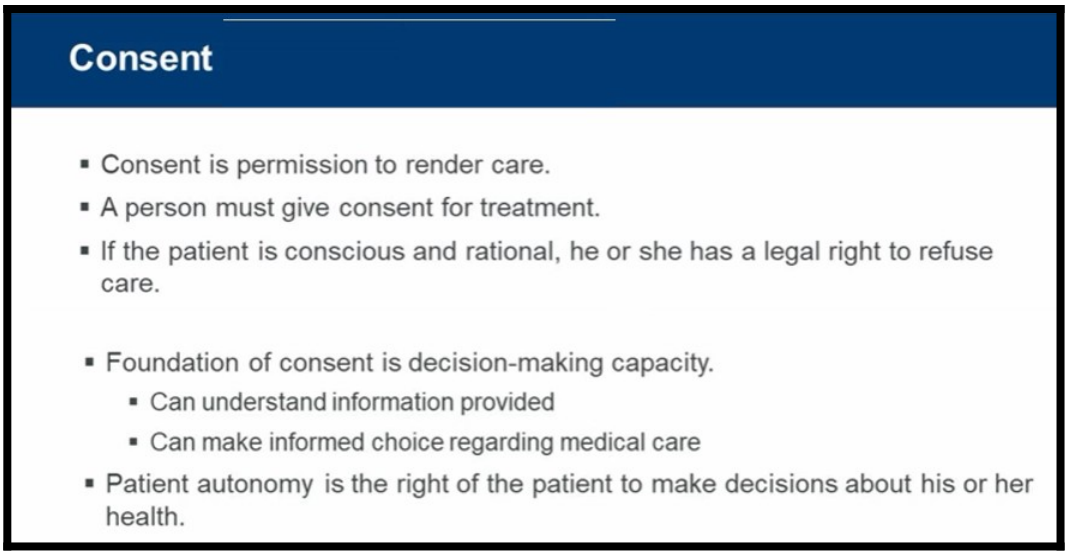

Consent
Consent is permission to render care.
A person must give consent for treatment.
If the patient is conscious and rational, he or she has a legal right to refuse care.
Foundation of consent is decision-making capacity.
Can understand information provided
Can make informed choice regarding medical care
Patient autonomy is the right of the patient to make decisions about his or her health.

***Figure 5**. Patients have the right to consent to medical treatment or to refuse medical treatment*

If I were a twenty-year-old kid, working as an EMT for $20/hour, I would be required to uphold a legal **duty to provide patient care**. What does that mean? It means that driving home on some snowy Sunday morning, if I see a family car rollover, I am required to pullover and check the welfare of passengers and provide medical assistance until someone on duty, of higher medical credential than I, arrives to assume care.

Once I pull over and establish care, I could not simply decide that I wanted a sandwich and leave the injured family alone, strewn all over the snowbank. That would be considered a crime called **patient abandonment**. That is the law, even at the lowest paid positions of healthcare. Those rules extend all the way up to the highest positions in healthcare. With more authority, comes more responsibility, not less. Do we see more or less adherence to the law at higher levels of authority in healthcare? I believe that we see less. Let's explore a recent example from my own personal experience.

Patient Experience #1. Lost access to insulin pump for 6 months in 2024 due to unintentional failures by the medical system

In 2024, An insulin pump manufacturer in California named Insulet stopped manufacturing their oldest model of Omnipod insulin pump. The pump's controller was commonly referred to by the model name *Omnipod Classic*, and it used a model of pod called *Omnipod Euros*. (Figure 6) Users were required to upgrade to a newer hardware model - either the Omnipod Dash or the Omnipod 5 model. The mandatory hardware upgrade would be free of

charge. I began an upgrade process to the Dash model of pump. (See figure 7)

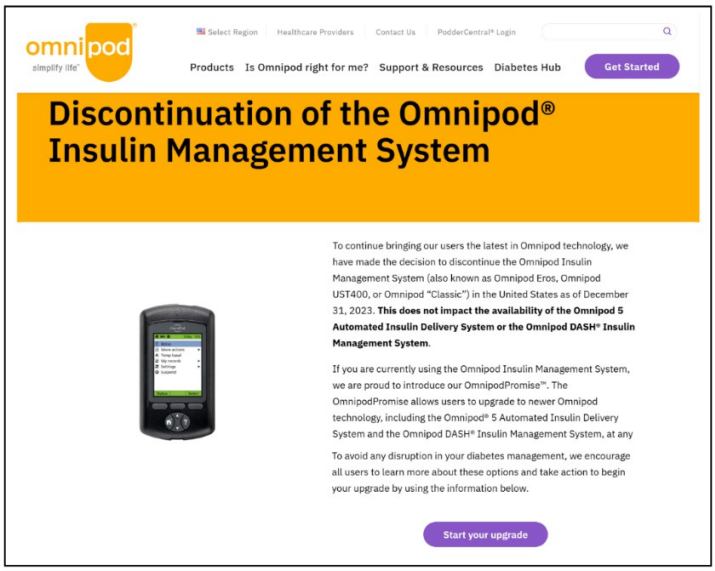

omnipod
simplify life
Select Region
Healthcare Providers
Contact Us
PodderCentral® Login
Products
Is Omnipod right for me?
Support & Resources
Diabetes Hub
Get Started
Discontinuation of the Omnipod® Insulin Management System
To continue bringing our users the latest in Omnipod technology, we have made the decision to discontinue the Omnipod Insulin Management System (also known as Omnipod Eros, Omnipod UST400, or Omnipod "Classic") in the United States as of December 31, 2023. This does not impact the availability of the Omnipod 5 Automated Insulin Delivery System or the Omnipod DASH® Insulin Management System.
If you are currently using the Omnipod Insulin Management System, we are proud to introduce our OmnipodPromise™. The OmnipodPromise allows users to upgrade to newer Omnipod technology, including the Omnipod® 5 Automated Insulin Delivery System and the Omnipod DASH® Insulin Management System, at any
To avoid any disruption in your diabetes management, we encourage all users to learn more about these options and take action to begin your upgrade by using the information below.
Start your upgrade

***Figure 6**. Discontinuation of the Omnipod Insulin Management System by Insulet [18]*

I received a new insulin pump controller from Insulet through the mail. (Figure 7) But that is only half of the equipment required to operate the device. I also required a supply of disposable Dash pods. Despite my doctor making numerous attempts (perhaps 25 attempts) to send a prescription to Walgreens, the second half of the medical equipment required to operate the pump was not made available until six months after my original device was no longer manufactured. During this six-month period, my doctor sent the prescription to a variety of pharmacies in Minnesota. I called the insurer, pharmacies, distributors, and the manufacturer daily in an effort to gain access to the equipment necessary to continue operating my device. I spent countless hours every day attempting to obtain information about why I could not access the equipment.

***Figure 7**. Insuet Omnipod Dash insulin pump system*

The only valuable information that I obtained came from a Durable Medical Equipment (DME) distributor in Iowa called VGM HomeLink. One of their customer service representatives, herself a type 1 diabetic, believed that the system failure stemmed from a change in the classification of the device from DME to “Nondurable medical equipment.” She described making every effort she could to alert insurers about the pitfalls associated with this classification change. This change in coding resulted in not even one pharmacy computer system maintaining a capable to supply the equipment. This reclassification also resulted in my inability to obtain equipment from a traditional DME distributor like VGM HomeLink.

The situation was finally resolved by calling Insulet (the device manufacturer in California). They shipped some Dash pods to a pharmacy in Fargo. That pharmacy then shipped them to a Walgreens located in Blaine, MN. I was able to successfully purchase them there.

In total, it took the medical system 6 months to fill one prescription for a device that I have been using continuously for 10 years. The level of irresponsibility and unreliability of the medical system is unprecedented. It represents a failure in duty to uphold care that is analogous to medical negligence.

Industry failures like this are so common as to hardly warrant a raised eyebrow from experience diabetics. But they result in death for the inexperienced who haven’t the faintest idea how to medically overcome a loss of access to insulin or insulin delivery system via their typical supplier. The amount of time that I dedicated to resolving this problem easily reached

20 hours per week. This example is representative of a system that is so highly disordered and unreliable that it becomes difficult to argue that it provides any value whatsoever.

During January 2024, I was commuting 30 miles between Anoka and Burnsville, Minnesota for work every day. On a snowy day through the heart of the city, that's a 2 ½ hour commute one way. When the medical system revokes my access to life sustaining prescriptions, devices, and medications, I need to immediately improvise a makeshift solution on my own. There is no support from professionals. I need to change the mechanisms through which I deliver insulin from an insulin pump to a syringe. That's a substantial change in treatment that requires immediate changes in medication dosages. It is a little dangerous, even for highly experienced diabetics like me.

Dramatic changes in treatment are executed more safely when they are planned and not the result of spontaneous medical system failures. It represents not only personal risk to me, but public safety risk because I had a 5-hour daily commute, round trip on a snowy day. If the medical system is so brittle and prone to failure that there is no way for it to maintain care consistently, then it is a better and safer option for me to forego any reliance on the formal medical system completely.

Alternatively, I am considering that the most practical option might be to peruse changes in state law that guarantee me access to syringes. Thirty-year-old insulins are available Over the Counter (OTC) from Walmart. Those two items (syringes and insulin), used in conjunction could guarantee me uninterrupted access to life preserving medication that the formal medical system is consistently unable to provide. That may be a preferable option when I know that I simply cannot dedicate 20 hours per week to babysitting the medical system and its inability to perform even basic responsibilities. It may be the safest option for me, and the public at large, to forgo medical care completely. I'll still need to pay insurance premiums in case of emergency, but I could absolve myself of any participation in the medical system if I had open access to syringes to deliver insulin.

Impacts of Monopolization on Industry Incentive to Innovate – Medical Device Collusion

In the Twin Cities, I see diabetic patients operate hacked medical devices with their own individually developed software solutions. Diabetic medical device innovation was forced to operate entirely outside of commercial

markets, independent from the regulatory structures built to protect patient safety. Patients in my hometown ran medical device software, for years, that didn't operate under the formal safety regulations of federal agencies like FDA but instead ran only under FDA's "good graces." The commercial medical device and insurance industry attempted to restrict patient and provider access to quality engineering in the hardware and software market. I am forced to ask the question, "In what sane, operational free market are patients forced to research, develop, test and build their own medical equipment for free using a Do It Yourself (DIY) approach because companies can't?" This is a reasonable question that causes one to wonder about the integrity of the medical markets.

10 years of digital patient advocacy provided me with extensive experience troubleshooting medical device hardware and software for the online patient community. This type of volunteer work helps fill in the many gaps left by traditional medical and healthcare systems. As one of the first 600 testers for Loop **Artificial Pancreas System (APS)**, I contributed data to the Jaeb research study to supplement informal FDA evaluation of if patient-built Artificial Pancreas System (APS) software for insulin pumps and Continuous Glucose Monitors (CGMs) should be allowed to exist. [4] Patients like Ben West and diabetic groups focused on software development, like Nightscout, negotiated with regulatory agencies like FDA for permission to release a large open-source software package to operate medical devices. [5,28, 31] It was used by thousands of diabetics on the internet. A large freeware project named Loop Artificial Pancreas System (Loop APS) was released by 2019 for all US models of insulin pumps and most blood glucose sensors. [6] I published a software safety evaluation and was using a patient-built system by late 2020. [7]

The first insulin pumps hacked by patients (a necessary precursor for medical device development) were Medtronic pumps. "Hacked" is a strong word for what occurred because the devices had no encryption. There wasn't much technical improvement in Medtronic insulin pumps from 2006 on, until patients took research and development into their own hands. You can see an early reference to this work to address a lack of innovation in the medical device space at the 2011 Blackhat conference, where diabetic Jay Radcliffe presents on the topic. [3]

Diabetics using patient-developed systems would occasionally notice one another in restaurants and spark up conversations. We called one another, "loopers." Loop was the first widely used APS system in the US. It served as proof of concept and forced development of commercial systems like the

Medtronic 780G and Insulet's Omnipod 5 insulin pumps. I recently spoke with a Minneapolis man who had an autistic son with Type 1 diabetes. He relied on that resulting commercial technology that was only available because of innovations by the diabetic patient community.

It's not that companies were incapable of performing the same quality of research and development that diabetic patients did. It's that they had no commercial incentive to innovate. In Minneapolis, we instead witnessed collusive efforts between Medtronic and United Heath Group (UHG) to restrict access to technological innovation. (Figures 4 and 5) UHG made statements that Medtronic insulin pumps were the only, "safe pumps," in direct contradiction to the following: 1.) FDA evaluations; 2.) Research published by the Diabetes Technology Institute; and 3.) The experiences of patients. [20] Insurers attempted to restrict access to only the least effective brand of insulin pump through the marketplace – that which was manufactured by Medtronic. These efforts were in response to, in part, a loss of market share driven by widespread disdain for their product by customers. Company efforts to circumvent all the freedom in the consumer market and the clinical preferences of patients and doctors are all too common. It's easier to "fix" a market than it is to innovate actual value into the economy. But this leaves American markets an empty shell of what they could be and disincentivizes commercial innovation.

When United Health Group and Medtronic collaborate to fix the market by restricting patient and provider access to market innovations, patients lose their right to either consent to or refuse treatment. That legal right is removed from the patient and is reallocated to the insurer. (Figures 8 and 9) An increasing number of insurers become incentivized to engage in similar unethical and potentially illegal practices. These efforts negatively impact on incentives to innovate in the marketplace.

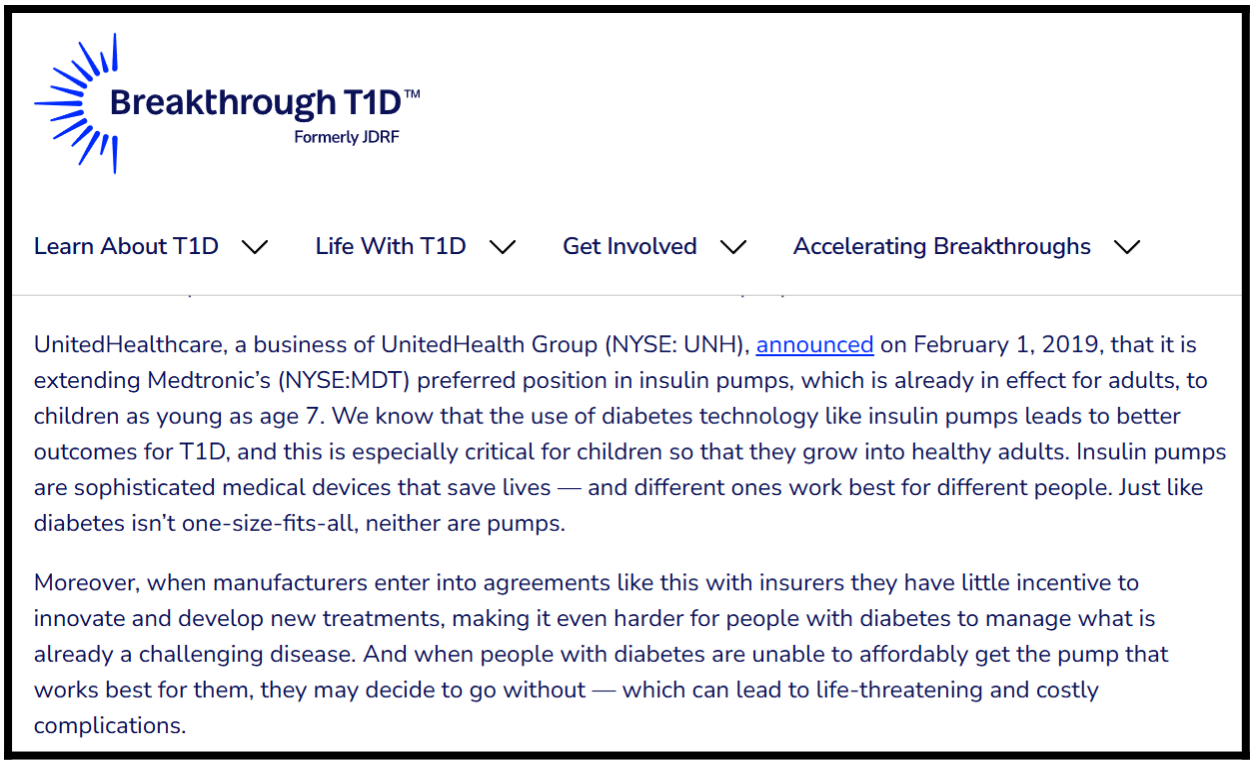

Breakthrough T1D™
Formerly JDRF
Learn About T1D
Life With T1D
Get Involved
Accelerating Breakthroughs
UnitedHealthcare, a business of UnitedHealth Group (NYSE: UNH), announced on February 1, 2019, that it is extending Medtronic's (NYSE:MDT) preferred position in insulin pumps, which is already in effect for adults, to children as young as age 7. We know that the use of diabetes technology like insulin pumps leads to better outcomes for T1D, and this is especially critical for children so that they grow into healthy adults. Insulin pumps are sophisticated medical devices that save lives — and different ones work best for different people. Just like diabetes isn't one-size-fits-all, neither are pumps.
Moreover, when manufacturers enter into agreements like this with insurers they have little incentive to innovate and develop new treatments, making it even harder for people with diabetes to manage what is already a challenging disease. And when people with diabetes are unable to affordably get the pump that works best for them, they may decide to go without — which can lead to life-threatening and costly complications.

Figure 8. *United Health Group prevents coverage for any insulin pumps other than those produced by Medtronic [13, 19]*

Fact Sheet
UnitedHealthcare
About the UnitedHealthcare and Medtronic Relationship
Working Together to Support People with Diabetes
UnitedHealthcare and Medtronic are working together to make a widely used and effective product available to our members while pursuing new ways to lower the overall cost of living with diabetes. Patient safety, service and cost were key considerations in our decision-making process to work with Medtronic, who will be designated the preferred provider of insulin pumps for UnitedHealthcare Commercial and UnitedHealthcare Community Plan (Medicaid) members starting on July 1.

Figure 9. *UHG 2019 statement regarding insurance restriction to only Medtronic insulin pumps [12]*

The timeline illustrated below in figure 10 shows that commercial innovation stalled out around 2006. Patients pick up the baton. Patients were largely spurred forward by the release of the Dexcom Continuous Glucose Monitor. The device enabled 288 blood glucose readings per day, or one reading every 5 minutes. It allowed patients open, unrestricted access to all their generated medical data and the freedom to analyze it however they deemed fit. [30] It placed control of the illness back in the hands of patients, instead of companies. Patients returned the favor in upcoming years by building tools for data analytics, remote monitoring, data integration, and networking together multiple medical devices into a single system. They began performing predictive analytics and finally closed loop systems that performed automatic insulin dosing with the option available for highly personalized, customized systems for each individual. The result of this work was large changes in the paradigm that surrounds type 1 diabetes and conventions for treating it. A list of patient developed software systems are provided in table 1.

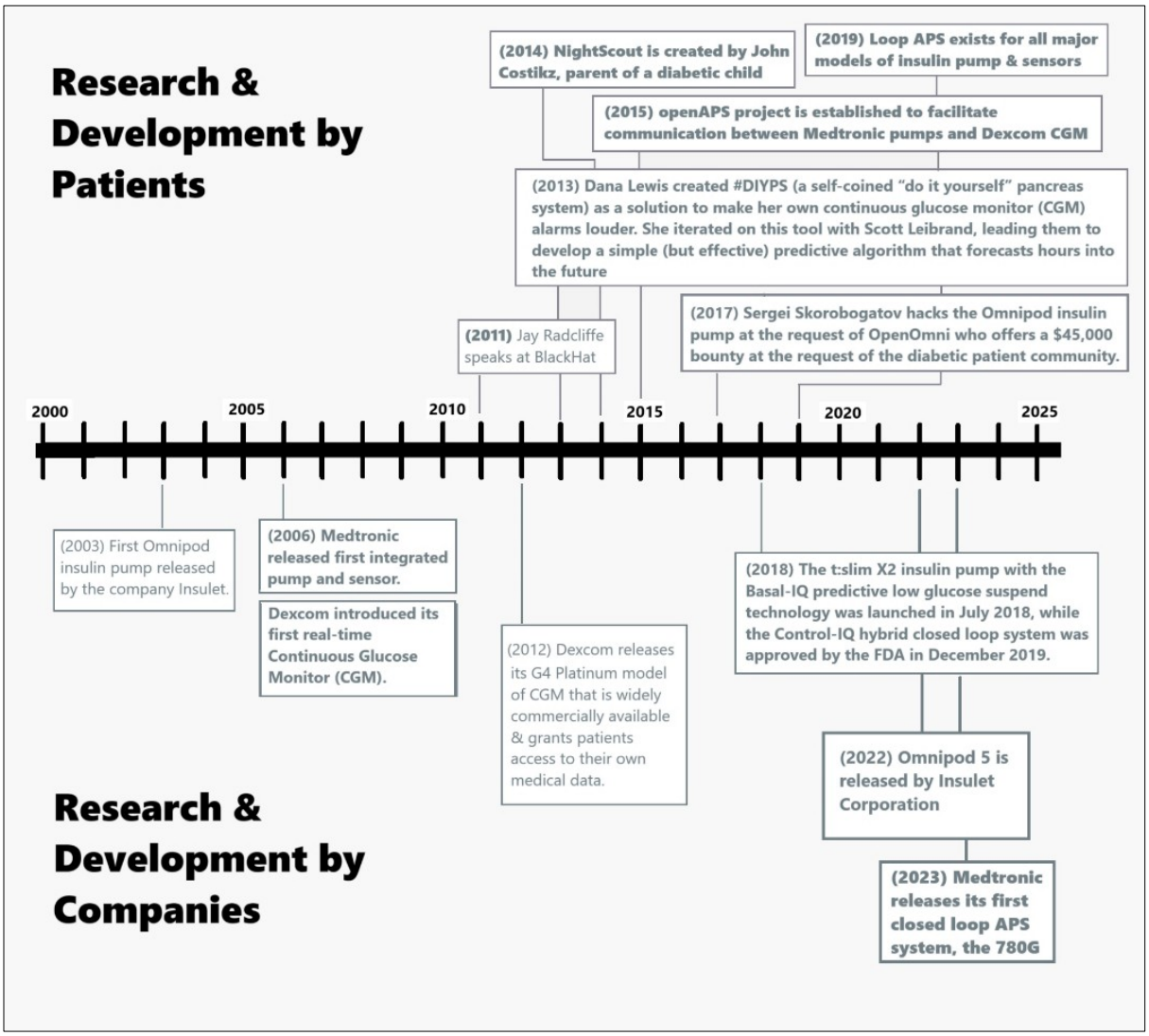

Research & Development by Patients
(2014) NightScout is created by John Costikz, parent of a diabetic child
(2019) Loop APS exists for all major models of insulin pump & sensors
(2015) openAPS project is established to facilitate communication between Medtronic pumps and Dexcom CGM
(2013) Dana Lewis created #DIYPS (a self-coined "do it yourself" pancreas system) as a solution to make her own continuous glucose monitor (CGM) alarms louder. She iterated on this tool with Scott Leibrand, leading them to develop a simple (but effective) predictive algorithm that forecasts hours into the future
(2011) Jay Radcliffe speaks at BlackHat
(2017) Sergei Skorobogatov hacks the Omnipod insulin pump at the request of OpenOmni who offers a $45,000 bounty at the request of the diabetic patient community.
2000
2005
2010
2015
2020
2025
(2003) First Omnipod insulin pump released by the company Insulet.
(2006) Medtronic released first integrated pump and sensor.
Dexcom introduced its first real-time Continuous Glucose Monitor (CGM).
(2012) Dexcom releases its G4 Platinum model of CGM that is widely commercially available & grants patients access to their own medical data.
(2018) The t:slim X2 insulin pump with the Basal-IQ predictive low glucose suspend technology was launched in July 2018, while the Control-IQ hybrid closed loop system was approved by the FDA in December 2019.
(2022) Omnipod 5 is released by Insulet Corporation
(2023) Medtronic releases its first closed loop APS system, the 780G
Research & Development by Companies

***Figure 10**. Timeline of innovation by companies (below timeline) and patients (above timeline) [8,10,11]*

Most companies engage in little or no development in their hardware, and no development in their software from 2006 on, except for Dexcom and Tandem. Tandem is a Canadian company that first began incorporating predictive capabilities into their commercial insulin pump. The timeline illustrates that medical device companies like Medtronic and Insulet did not develop APS systems - patients did, starting in 2013. Patients wrote all the algorithms and the software for class III (highest risk) medical device systems. Technology developed by patients (top of the timeline) forced the hand of commercial medical devices (bottom of timeline) in the United States by 2019, at which time patients were operating APS software systems for all major model of insulin pump hardware.

Patient Developed Systems			
Software Development Group	**Link to Project**	**Year Developed**	**Purpose**
Nightscout	nightscout.github.io	2013	Remote monitoring software primarily built for the purpose of allowing a parent to monitor the blood sugars of their T1 children
Tidepool	tidepool.org	2013	Data analysis tool
DIYPS	https://diyps.org	2013	Initial purpose was to make continuous glucose monitor (CGM) alarms louder. Eventually, it became a full, DIY closed loop artificial pancreas that is open source for others to use as well.
XDrip	xdrip.readthedocs.io/en/latest/#what-is-xdrip	2014	xDrip+ is an unofficial and independent Android app which works as data hub and processor between many different devices.
OpenAPS	openaps.org	2015	First Artificial Pancreas System (APS) in the U.S. that used system controls. OpenOmni offered a $45,000 bug bounty for hacking of Insulet's Omnipod insulin pump.
Loop APS	loopkit.github.io/loopdocs	2019	First widely used APS system in the U.S. that served as proof of concept for the Medtronic 780G and Insulet's Omnipod 5 APS insulin pumps. Ran on Apple iOS.

***Table 1**. Opensource software systems currently in use by patients*

Commercial systems were engineered and brought to market 3 years after the patient-built *Loop APS*. Insulet's Omnipod 5 APS system was commercially released in 2022. Medtronic released their 780G in 2023. [8] The open-source Loop APS project was officially put through FDA by Tidepool to form Tidepool Loop and granted formal approval in 2023, but it was already widely used among the patient community since 2019, prior to formal FDA evaluation. [27]

Patients are both forced, and motivated, to continue working on healthcare and medical innovation, despite great personal risk, time investment, and financial burden. Threats to life and limbs, by blocking innovation, prompted FDA to side with the patient community. Over the course of patient efforts to

bring technical innovation into the healthcare markets, Abbott Labs was the only company to threaten the patient community with lawsuit. [24] (See figure 11) That might have to do with the fact that it is a complicated matter to sue one's own customers for performing your R&D and product development for free. Technical details surrounding the progression of research and development on the patient side are available by cloning this GitHub repo and downloading the paper located here. [9] I include an excerpt of page 25 from that paper here to better explain *why* patients are willing to dedicate incredible resources and assume legal risk to overcome failures in the commercial market:

> **"Early development in the Nightscout project began when Dana Lewis, a type 1, was having severe low blood sugars overnight while she was sleeping. Her boyfriend, an engineer, modified an early model of Dexcom CGM to transmit data to his cell phone. This required modification in the $6,000 device's external casing, which invalidated the warrantee, and involved some financial risk. [11] Despite the risk, type III diabetics (the nickname given to diabetic friends and family members who play supportive roles in managing the illness), particularly the parents of young type 1 diabetic children, wanted long range data access. Parents desperately wanted data access while their children were at school and adopted the device modifications. This was particularly important for the parents of young children who may lack the ability to recognize or communicate adequately about their condition."** [9]

You will be hard pressed to find examples from other American industries where customers perform all their own research, development, and testing of products that are then sold back to them at highly inflated prices.

Abbott Laboratories Sends Heavy-Handed Copyright Threat To Shut Down Diabetes Community Tool For Accessing Blood-Sugar Data

from the *not-very-sweet,-not-very-clever* dept

Wed, Dec 18th 2019 12:03pm - Glyn Moody

Copyright

One of the most important recent developments in the world of diabetes has been the arrival of relatively low-cost continuous blood glucose monitors. These allow people with diabetes to take frequent readings of their blood sugar levels without needing to use painful finger sticks every time. That, in turn, allows users to fine-tune their insulin injections, with big health benefits for both the short- and long-term. The new devices can be read by placing a smartphone close to them. People use an app that gathers the data from the unit, which is typically placed on the back of the upper arm with an adhesive.

***Figure 11**. Abbott threatens lawsuit against patients for trying to access their own personal medical data via their own personal medical devices [24]*

Coercion of Doctors by Insurers

I have reached the point as a patient, where there is no medical care being exchanged or facilitated through the patient and provider relationship. Every

interaction between myself and my doctor is the result of forced coercion. Although I receive no value from the care I am forced to participate in, I am not allowed to leave the relationship because they will revoke my access to insulin, and I will die. The patient-doctor relationship is an empty shell that both my doctor and I are forced to live inside, at the bequest of the insurer. A lot of money changes hands. But there is no actual patient care taking place. Both financial and physical coercion are used to force my participation. I fear that the path of medical innovation and the path of the practice of medicine have so diverged that providers no longer have the skills or knowledge required to provide patient care. While this is not dangerous for sophisticated type 1 diabetic patients who may have managed the practical day in and day out of their illness for decades, it is very dangerous for the newly diagnosed.

The insurer uses threats of retaliation to prevent patients from exercising their freedom to make informed personal medical decisions and to prevent providers from exercising their duty to provide care. There is, in many cases, no medical rational behind treatment. Medical decisions are made exclusively by, and for the benefit of, the insurer.

Patient Experience #2. Intentional medical system failures engineered by insurers in response to passage of Minnesota state law S.F. 2744

The primary purpose of this example is to illustrate that medical decision making comes from the insurer, not the doctor. I have been receiving three months of pump supplies at a time, for years. There is no possible medical reason for cutting my access to supplies in half. The only possible rationale is changes in state law that were implemented on Jan 1st, 2025. (See figure 12)

For the last 30 years that I have been a diabetic, standard practice has been that diabetics are required to attend one clinic visit per year with a doctor. We do this because otherwise they take away our insulin access and we die. The notion that taking away a diabetic's access to insulin is ***ever*** in accordance with medical ethics, and *Do No Harm* principles, is questionable at best. But insurance likes us to see a doctor annually and that has been the standard for 30 years. The doctors write prescriptions that are valid for a one-year period.

Pharmacies typically fill pod prescriptions for a three-month quantity of supplies at a time. Figure 13 is an image of the last pod prescription I filled in 2024 before Senate Finance 2744 became state law. (Figure 12) It allocates

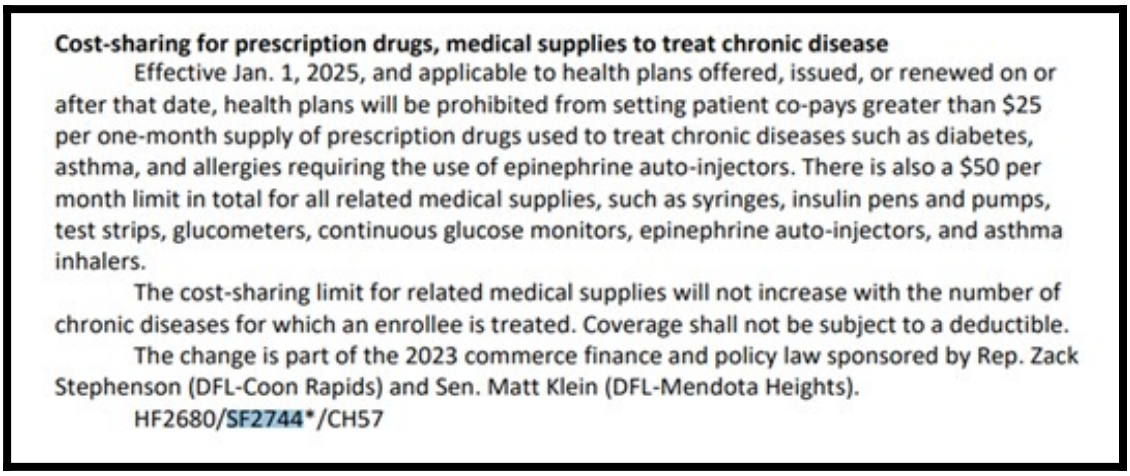
30 insulin pump pods. Each pod lasts three days. It is a three-month supply of pod, as shown below:

30 pods x (3 days/pod) = 90 days

Immediately after S.F. 2744 went into effect, the amount of pod supplies that I was allocated was cut in half to a 45-day (6 week) supply of 15 total pods. Each box contains 5 pods. (Figure 13)

3 boxes of pods x (5 pods/box) = 15 pods

15 pods x 3 days = 45 days, or 6 weeks.



Cost-sharing for prescription drugs, medical supplies to treat chronic disease

Effective Jan. 1, 2025, and applicable to health plans offered, issued, or renewed on or after that date, health plans will be prohibited from setting patient co-pays greater than $25 per one-month supply of prescription drugs used to treat chronic diseases such as diabetes, asthma, and allergies requiring the use of epinephrine auto-injectors. There is also a $50 per month limit in total for all related medical supplies, such as syringes, insulin pens and pumps, test strips, glucometers, continuous glucose monitors, epinephrine auto-injectors, and asthma inhalers.

The cost-sharing limit for related medical supplies will not increase with the number of chronic diseases for which an enrollee is treated. Coverage shall not be subject to a deductible.

The change is part of the 2023 commerce finance and policy law sponsored by Rep. Zack Stephenson (DFL-Coon Rapids) and Sen. Matt Klein (DFL-Mendota Heights).

HF2680/SF2744*/CH57

Figure 12. *S.F. 2744 became Minnesota law on Jan 1st, 2025*

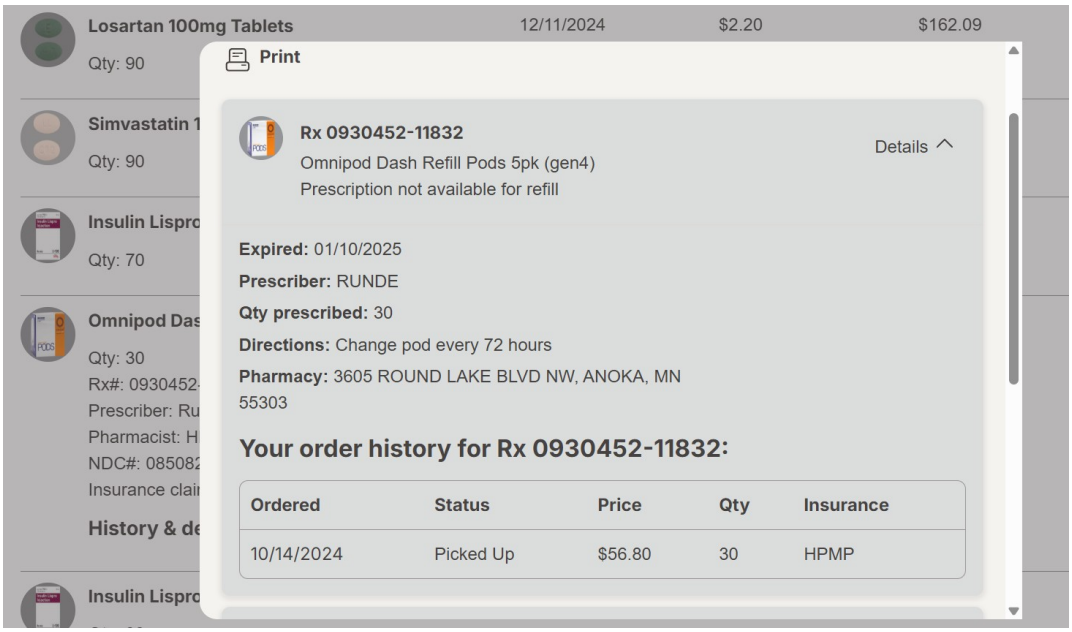


Figure 13. *3 months of insulin pump pods per pickup, prior to S.F. 2744 becoming law on Jan 1st, 2025*

Figure 14. *Six weeks 3 of insulin pump pods per pickup after S.F. 2744 becomes law on Jan 1st, 2025*

There is no medical reason to suddenly change the manner that pump supplies are prescribed and distributed. This is the insurer (HealthPartners) acting through the doctor to game the system to their advantage after passage of S.F. 2744. This occurs, not just in pumps, but in every script we fill. The doctors are suddenly writing prescriptions to decrease access to medical equipment and medication. This creates the highest possible administrative burden, the smallest financial benefit possible for patients, and the highest medical risk to patients. There is absolutely no medical rationale for this. In this way, insurers perform a role in medicine that is not unlike an intoxicated bargoer interfering with patient care, delivered by paramedics during a car accident, while fleeing the Minneapolis's Warehouse district at bar close. They should be arrested and charged. Let's create an analogy to a real-world example in street medicine for legal clarification of the insurer's actions.

Many a paramedic from the local streets could tell you a late-night tale of when, at bar close, a terrible accident occurred. As the medics knelt beside the bloodied victims, a drunk man adorned in a vomit covered suit staggered forth from the car that had moments ago mowed people down, claiming that they were, "friends of his," and that they were, "fine." One medic begins to raise himself slowly, invisibly, to not attract undue reaction from the drunk man. He will instead stand as a barrier between the partner providing patient care, his patients, and the approach of the intoxicated threat. "Get away from them!" the drunk man shouts, suddenly enraged by the scent of vomit, "I'll handle this!" This is an example of interference with a peace officer (the medics) and ought to result in arrest of the drunk man. The paramedics have a legal duty to provide patient care unless the threat of physical harm becomes insurmountable, and police are required to secure the scene.

While the comparison of interference by a drunk bystander at a car accident to interference by an insurer in a doctor's prescription may seem melodramatic, I argue that the magnitude of impact from the prior example is no less than the magnitude of impact from the later example. The scale of impact in the prior example, while impactful for the patients on scene, is far exceeded by the magnitude of patient harm identified in the later example because millions of Americans are repeatedly impacted every day.

To investigate potential reasons that a doctor may be under pressure to prescribe in a manner that is not in the patient's best interest, I asked a doctor. He responded with the following,

> **“Generally, insurers can effect prescribing habits for regular medication by:**
> **1.) Listing preferred medications in their formulary [These alternative medications may/may not be as effective.]**
> **2.) Putting up admin barriers - any script longer than " x" days requires a prior auth.**
>
> **In the interests of time (which doctors do not have), the easiest route is often taken on a day-to-day real-world basis. If 6-month scripts were going to cause admin headaches for a chronic disease, then that is a shame on the insurer/PBM.”**

Coercion isn’t isolated to relationships between patients and insurers. It exists between doctors and insurers. Doctors have been castrated and have no professional agency to practice. Dr. Howard Green writes about this from over the other side of the fence very succinctly in his paper titled *American Physicians are Putzes*, from 2016. He writes, “Wittingly and unwittingly, the American Physician Putz has enabled the ascendancy of the following industries at the expense of their patients and themselves…” He lists the following as problematic: 1.) Health Insurance Industry; 2.) Pharmaceutical Industry; 3.) Medical Malpractice Industry; 4.) Publishing Industry; 5.) Hospital Industry; 6.) Electronic Health Records (EHR) Industry; 7.) Organized Medicine Industry; 8.) Board Certification Industry; and 9.) Elected Representatives. [32] A multipart investigation in STAT News from July of 2024, titled *Health Care’s Colossus* discusses these issues in depth, citing that,

> **“UnitedHealth Group started out as a small, Minnesota health insurance company and has since morphed into a modern-day Standard Oil, exerting unmatched dominance over health care in the United States.**
>
> **It’s no secret that UnitedHealth is a colossus: It’s the country’s largest health insurer and the fourth-largest company of any type by revenue, just behind Apple. And thanks to a series of stealthy deals, almost 1 in 10 U.S. doctors — some 90,000 clinicians — now either work for UnitedHealth or are under its influence, more than any major clinic chain or hospital system.” [33]**

As a patient, it is easy to believe that the Corporate Practice of Medicine (CPOM) prohibition has failed us entirely. [34, 35] (Figure 15)

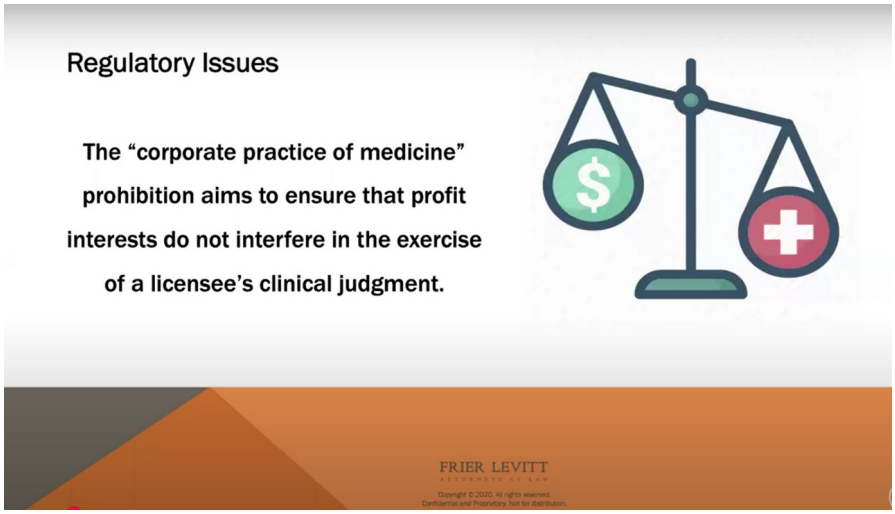

Regulatory Issues
The “corporate practice of medicine” prohibition aims to ensure that profit interests do not interfere in the exercise of a licensee’s clinical judgment.
FRIER LEVITT

***Figure 15**. Corporate Practice of Medicine Prohibition [34]*

Pharma & PBM Antitrust Efforts in Minnesota

One of the common threats made by insurers, manufacturers, and doctors to patients is that they will stop providing access to prescribed, life preserving medications if patients don’t meet their every demand. There is good reason to believe that these threats are real because they so commonly fail to provide me with access, even when I ***do*** meet all their demands. Manufacturers have threatened to stop producing insulin. Doctors threaten to stop writing prescriptions. Insurers install insurmountable and regular bureaucratic roadblocks to prevent patients from obtaining insulin and insulin delivery devices. Several concrete examples of how these efforts at physical and financial coercion play out in practice are included in my “Patient Experience” subsections of this paper within the sections titled, “Impacts of Monopolization on Patient Care,” “Coercion of Doctors by Insurers, and “Market Consolidation in the Form of Pharmacy Closures.” Pharma’s Eli Lilly lobbyists are so comfortable with this arrangement that they casually refer on LinkedIn to their diabetic customers as, “highly profitable and exploitable,” during active antitrust litigation between themselves (large insulin manufacturers), the three largest PBMs in the country, and the State of California. [36] (Please see figure 16)

Minnesota was the first state to file a lawsuit against the insulin manufacturers in 2018. [37,56] Settlement was reached with Eli Lilly and Sanofi in 2024 to guarantee, “…All Minnesotans, with or without insurance, can buy…insulin products for $35 per month for the next five years.” [51, 53, 54] It assures no price gouging until 2029 for Minnesota residents. The lawsuit continued against insulin manufacturer Novo Nordisk, “alleging they

deceptively priced their insulin products, requiring uninsured and underinsured Minnesotans to pay astronomically high out-of-pocket costs based on the list price of the drugs," but reached a similar settlement in 2025. [51, 52]

Minnesota was the first state to call the Pharmacy Benefit Managers (PBMs) into state hearings, which I attended. The air was heavy with parental grief. It was attended by the parents of Alec Smith, a relatively newly diagnosed insulin dependent diabetic who died after insulin rationing. [55] Minnesota began state reporting, licensing and data collection on PBMs in 2019. [50] This year, they were the first state to begin data collection on 430B. [57]

The Midwestern experience is littered with young men dying of highly treatable chronic illnesses. That is partially attributable to our culture and the shame of young men needing to ask for money from their parents. A lot of young men with the best of intentions would rather die than ask for $300 from their mothers to cover insulin costs and they do. I know grown women who have sold their homes to buy insulin. Young men can't possibly understand the magnitude of the forces stacked against their survival and they view it through the lens of personal failure. No one in the medical system took the time to explain the risks of not taking insulin to Alec Smith. That is a basic responsibility. No one took the time to explain the risk that insulin is *very* expensive, equivalent to what he pays for rent and that if he ran into difficulty (which he obviously would because *every* diabetic patient encounters this), he could simply travel down to his local Walmart and buy insulin without a prescription for $20-$40. It amounts to medical negligence. Everyone in the system is taking grift and can't be bothered to fulfill even their most basic professional responsibilities. That's the problem of easy money. It drains away American competence.

Trying to break apart the monopolies has been a process. It's important to remember that Americans haven't done this since the time of the rail barons. There is no living memory of how to do it. For years, the "PBM problem" had been bane of diabetics inside our internet chatrooms. The first reference to 'PBM' there was by Scott Strumbello in June of 2008, in a post he titled, "New Healthcare Plans and Our Dysfunctional Medical System…Urg!" [58, 59] I'm younger than Scott, so by the time I arrived to inquire deeply about medical costs and how I might survive financially, the guys were resigned – willing to explain the details, but also ready to provide unsettling reassurance that, "Nothing would ever be fixed." I, still bloated with the baby fat of relentless

optimism that comes from being young and naïve, believed that while it was the World's most terrible problem, it might not be impossible to fix.

Years later, I drove to Rochester, Minnesota in hopes of seeing the first person whom I had ever encountered discussing the "drug pricing problem", in person. It was Dr. S. Vincent Rajkumar, a Professor of Medicine in Hematology at Mayo Clinic. [60] You can still see his presentation online and hear my CGM beeping irritatingly in the background. Mayo grants their doctors a higher level of authority and autonomy that is not often afforded to conventional doctors. He went on to explain that he had trouble practicing medicine because of the inflated costs of cancer drugs and that diabetics were in the best position to prove market fixing in the market because we had the most data. He would go on to advise the diabetics and the State of Minnesota when they sued the insulin manufacturers.

You can find evidence of this state history in the documentary titled ***Pay or Die***, produced with help from with the family of Alec Smith, Dr Rajkumar, and Quinn Nystrom of a diabetes advocacy group *Insulin 4 All*. [61] It's through this path that you see the seeds of intersecting policy interests that exist today between diabetics, oncology, and independent pharmacists for PBM reform. Independent pharmacists just released a movie, titled ***Modern Medical Mafia***. [63, 62] The doctors have a movie coming out called ***Suck it Up, Buttercup*** that will form a trilogy. [64] Minnesota is a large source of the "Monopoly problem," but it is also a source of attempts to find solutions. [65]

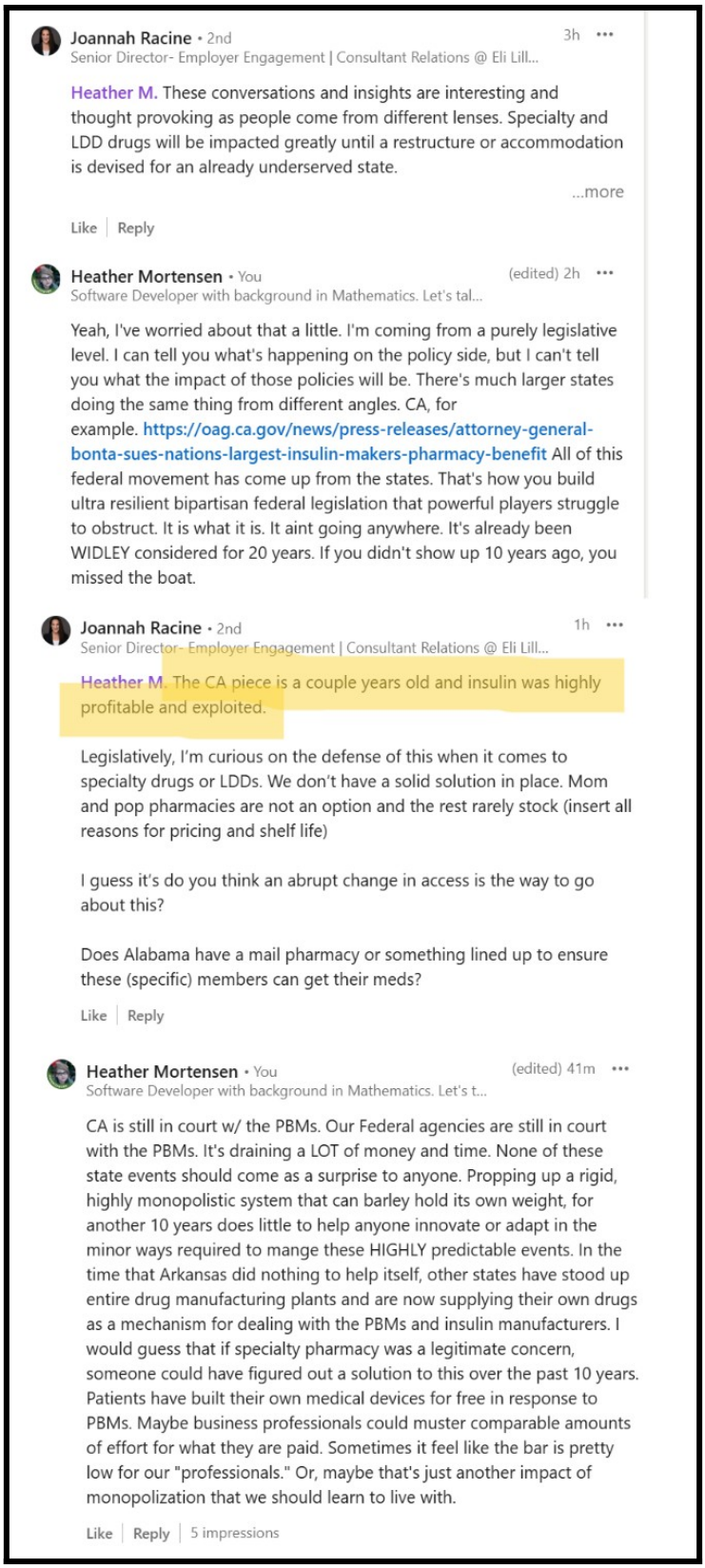

Joannah Racine • 2nd
Senior Director- Employer Engagement | Consultant Relations @ Eli Lill...
3h
Heather M. These conversations and insights are interesting and thought provoking as people come from different lenses. Specialty and LDD drugs will be impacted greatly until a restructure or accommodation is devised for an already underserved state.
...more
Like | Reply
Heather Mortensen • You
Software Developer with background in Mathematics. Let's tal...
(edited) 2h
Yeah, I've worried about that a little. I'm coming from a purely legislative level. I can tell you what's happening on the policy side, but I can't tell you what the impact of those policies will be. There's much larger states doing the same thing from different angles. CA, for example. https://oag.ca.gov/news/press-releases/attorney-general-bonta-sues-nations-largest-insulin-makers-pharmacy-benefit All of this federal movement has come up from the states. That's how you build ultra resilient bipartisan federal legislation that powerful players struggle to obstruct. It is what it is. It aint going anywhere. It's already been WIDLEY considered for 20 years. If you didn't show up 10 years ago, you missed the boat.
Joannah Racine • 2nd
Senior Director- Employer Engagement | Consultant Relations @ Eli Lill...
1h
Heather M. The CA piece is a couple years old and insulin was highly profitable and exploited.
Legislatively, I'm curious on the defense of this when it comes to specialty drugs or LDDs. We don't have a solid solution in place. Mom and pop pharmacies are not an option and the rest rarely stock (insert all reasons for pricing and shelf life)
I guess it's do you think an abrupt change in access is the way to go about this?
Does Alabama have a mail pharmacy or something lined up to ensure these (specific) members can get their meds?
Like | Reply
Heather Mortensen • You
Software Developer with background in Mathematics. Let's t...
(edited) 41m
CA is still in court w/ the PBMs. Our Federal agencies are still in court with the PBMs. It's draining a LOT of money and time. None of these state events should come as a surprise to anyone. Propping up a rigid, highly monopolistic system that can barley hold its own weight, for another 10 years does little to help anyone innovate or adapt in the minor ways required to mange these HIGHLY predictable events. In the time that Arkansas did nothing to help itself, other states have stood up entire drug manufacturing plants and are now supplying their own drugs as a mechanism for dealing with the PBMs and insulin manufacturers. I would guess that if specialty pharmacy was a legitimate concern, someone could have figured out a solution to this over the past 10 years. Patients have built their own medical devices for free in response to PBMs. Maybe business professionals could muster comparable amounts of effort for what they are paid. Sometimes it feel like the bar is pretty low for our "professionals." Or, maybe that's just another impact of monopolization that we should learn to live with.
Like | Reply | 5 impressions

Figure 16. *Eli Lilly lobbyist casually refers to customers as "highly profitable and exploitable" on April 23, 2025*

Impact of Monopolization on Technology Quality

One of the most insidious impacts of a lack of antitrust enforcement is the impact of the quality of our technology. Today, technology is the vehicle through which individual rights and the law are enforced. Let's explore a few examples of how that plays out, for patients, in practical reality.

Diabetic Technology Example #1. Glucometers

Glucometers, also known as Blood Glucose Machines (BGMs) or Blood Glucose Monitor Systems (BGMS) have existed as the fundamental device for patients, emergency responders, and medical staff to test blood sugar concentration in a person's blood since the 1980s. [22] In 2017, The Diabetes Technology Society (DTS) published an accounting of the number of Blood Glucose Machines currently available through the commercial market that met FDA criteria for accuracy. The article was titled, *Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors*. It found that, "The results were that only 6 of the 18 BGMSs passed all 3 times and received the Seal of Approval." At the time of this publication, this was not advanced or sophisticated technology. This was technology that had existed for 40 years. [21] If this is used as a baseline for evaluation of quality in American healthcare technology, loss of confidence by the American public seems justified. Diabetic patients regularly test glucometers against one another as a mechanism for double checking device accuracy. If patients can do it, then commercial manufacturers can do it. The fact that the market requires support and initiative from a private group like DTS to perform Verification and Validation (V&V) on technology from the 1980s, and bring that testimony to the federal government, indicates the market may not be performing adequately.

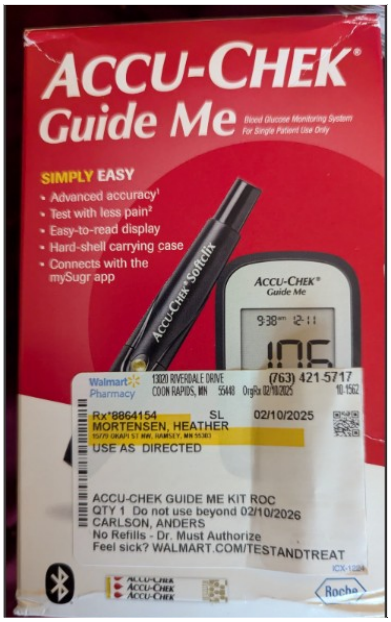
Although the DTS study is too old to make direct correlation to current glucometer models, it does illustrate brands from all major manufacturers still in use. I was prescribed an Accu-Check model most recently by my doctor. Both older models of Accu-Chek models pass in the DTS study of 2017. One is shown in the second row of the table illustrated in figure 17. It passes tests run for accuracy by DTS. But so does one of the Over-The-Counter (OTC) models (ReliOn) sold at Walmart. It is shown in the third row of the table. A second ReliOn brand meter, manufactured by Abbott, does not pass. It is shown in the seventh row of the table in figure 17.

Decreased regulations on a piece of 1980s technology might be warranted. It's very difficult to imagine a scenario where someone might use a

glucometer for nefarious purposes. Requiring a prescription for some brands, and not others, implies that prescriptions themselves might not be necessary in this case. The only purpose might be to inflate the price. A ReliOn brand meter is available OTC at Walmart for only $20. The nearly identical device shown in figure 17, when sold via a doctor, a prescription and insurance is $97.53. Somehow, simply purchasing the device via the traditional medical system increases the price fivefold.

			Study 1			Study 2			Study 3			Overall				
Brand	Blood Glucose Monitor	Test Strip	N	Percentage Compliant[†]	Pass/ Fail	N	Percentage Compliant	Pass/ Fail	N	Percentage Compliant	Pass/ Fail	Passes out of 3 Studies	Seal of Approval?	Valid Trials	Compliant N	Compliant %
Bayer	Contour Next	Contour Next	98	99%	PASS	101	100%	PASS	113	100%	PASS	3	YES	312	311	100%
Roche	ACCU-CHEK AVIVA Plus	ACCU-CHEK AVIVA Plus	97	97%	PASS	101	100%	PASS	113	98%	PASS	3	YES	311	306	98%
Arkray	Walmart ReliOn Confirm (Micro)	ReliOn Confirm/micro	100	96%	PASS	114	96%	PASS	103	99%	PASS	3	YES	317	307	97%
⋮													⋮			
LifeScan	OneTouch Verio	OneTouch Verio	108	87%	FAIL	106	98%	PASS	105	91%	PASS	2	NO	319	294	92%
Prodigy	Prodigy Auto Code	Prodigy No Coding	98	86%	FAIL	101	92%	PASS	113	93%	PASS	2	NO	312	282	90%
LifeScan	OneTouch Ultra2	OneTouch Ultra	97	92%	PASS	101	84%	FAIL	113	94%	PASS	2	NO	311	280	90%
Abbott	Walmart ReliOn Ultima	ReliOn Ultima	107	96%	PASS	106	97%	PASS	106	75%	FAIL	2	NO	319	285	89%
Bayer	Contour Classic	Contour	108	95%	PASS	106	85%	FAIL	106	86%	FAIL	1	NO	320	284	89%

Figure 17. *Diabetes Technology Society "Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors" [21]*



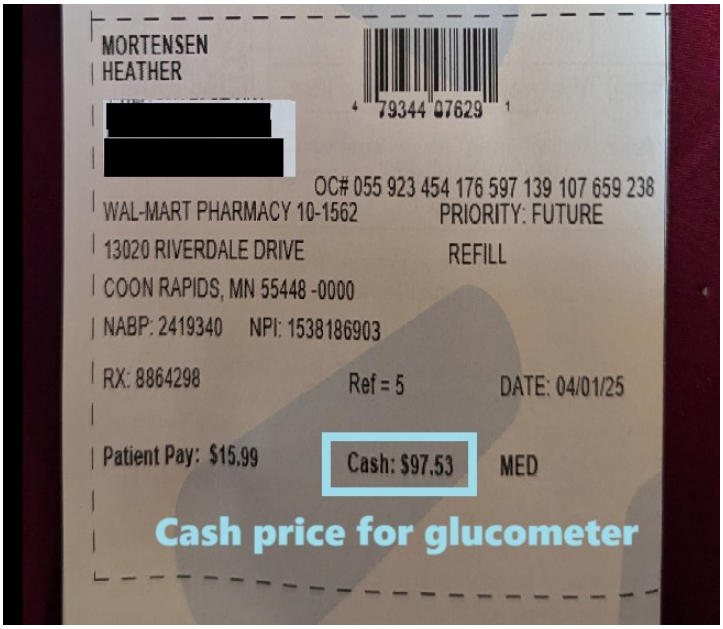
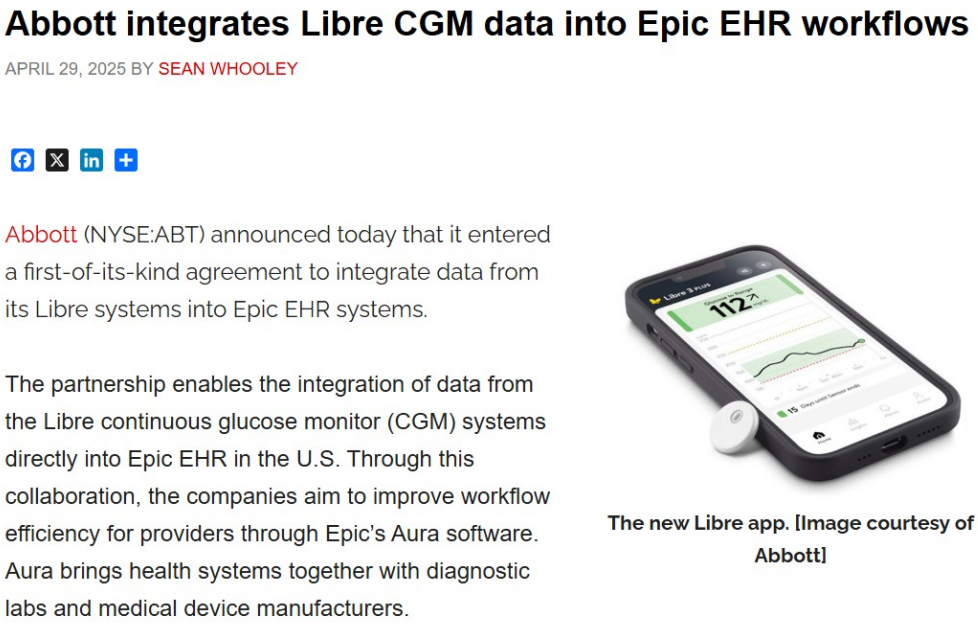


***Figure 18**. Detail of figure 14: Accu-Check Guide Me Glucometer OTC cash price $97.53*

Diabetic Technology Example #2. EPIC

Last month, Epic (a major vendor of software for electronic medical records used by medical practitioners) announced that they will allow diabetic medical data to be uploaded from diabetic medical devices like insulin pumps and Continuous Glucose Monitors (CGM) into Electronic Medical Record (EMR) software. [23] A link between Epic and Abbott's Libre CGM allows doctors to access patient data. (Figure 19) Libre has existed since 2015.



Abbott integrates Libre CGM data into Epic EHR workflows

APRIL 29, 2025 BY SEAN WHOOLEY

Abbott (NYSE:ABT) announced today that it entered a first-of-its-kind agreement to integrate data from its Libre systems into Epic EHR systems.

The partnership enables the integration of data from the Libre continuous glucose monitor (CGM) systems directly into Epic EHR in the U.S. Through this collaboration, the companies aim to improve workflow efficiency for providers through Epic's Aura software. Aura brings health systems together with diagnostic labs and medical device manufacturers.

The new Libre app. [Image courtesy of Abbott]

***Figure 19**. Abbott and Epic promise to integrate so that doctors can access basic patient data [23]*

CGMs collect up to 288 blood sugar readings per day. It's difficult to analyze that much data without software. See table 1 (below) for a list of dates of when diabetics were able to incorporate data from all their medical devices into a piece of software – ten years ago. It raises question like, "What the hell has industry been doing the past ten years?", "If patients can do it for free, why can't industry do it for money?", "Why isn't industry motivated to innovate?", "Why are we paying industry so much money when patients are doing all the software development work for free?"

Table 1 on page 15 shows that patients were able to innovate software solutions that combined every major brand of insulin pump and blood glucose sensor between 2013 and 2018. Why then could EPIC, a software company that specializes in Electronic Health Records (EHR) not accomplish this until 2025? Are the markets unwilling to innovate or are the markets unable to innovate?

Patient Experience #3. Blood Glucose Data Analytics

Questions that get raised can be profoundly troubling, like "Is industry qualified to provide medical care?" and "What sort of care are they providing when industry's leading EHR won't enable doctors to access diabetic medical data?" Do Doctors even have an ability to analyze this data? Or, have the

paths of medical innovation and medical practice so diverged that they have become completely disconnected from advancements that have taken place over the past 20 years?

I cannot answer these questions for anyone other than myself, but I would never allow a doctor to control my insulin dosages. No diabetics that I know, who are worth their salt allow their doctor to adjust their insulin dosages. Allowing my doctor to adjust my medications would constitute life threateningly bad judgement. This is a real problem for the newly diagnosed who rarely receive any training on how to analyze blood glucose data or adjust their insulin dosages, which require regular adjustments.

Abbott was the only medical device company to threaten lawsuit against the patient community for the projects listed in table 1. [24] (figure 9) It raised real questions like, “In what reality is *my* personal medical data that I collect, at great financial expense, through my own blood, sweat, and tears actually owned by Libre?” What good is that data if I am not allowed to analyze it? Should medical device developers feel entitled to restrict patient access to their own medical data and prevent them from using software tooling to analyze continuous real time data?

Good data analysis requires the most complete dataset possible and all sorts of information that isn’t collected by the sensor. For example, what food did I eat and at what time of day? Was I participating in physical activity? What is my comfort for risk this afternoon? If I am commuting home, across the city in heavy construction traffic with no A/C on a 95-degree day and yesterday I saw a woman standing in the middle of the interstate holding a baby when her car broke down in the heat, then I might want to run my blood sugar a little higher for reassurance that I am going to be clear headed and at the top of my game during my commute. Doctors simply do not have access to data like that.

Doctors are not in a great position to analyze blood glucose data. They do not even have access to complete data sets necessary for analysis worth its salt. They do not do that work. Patients do. Figures 20 and 21 illustrate one day of data collection performed by *me* in an effort to perform necessary testing required adjust basal (background) insulin dosages and bolus (insulin administered at meals) dosages on February 14th, 2025. Figure 22 illustrates another day of data collected on February 19th, 2025. Two weeks of data are the standard for analysis of blood glucose data.

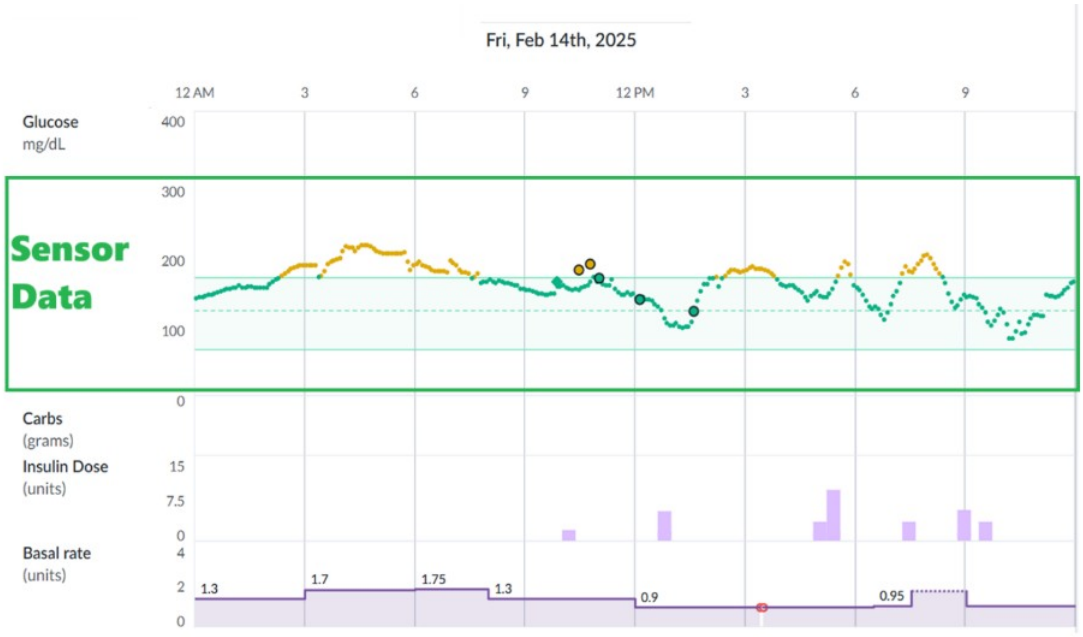


***Figure 20**. Integrated Dexcom CGM and Omnipod insulin pump data output from a software named Glooko*

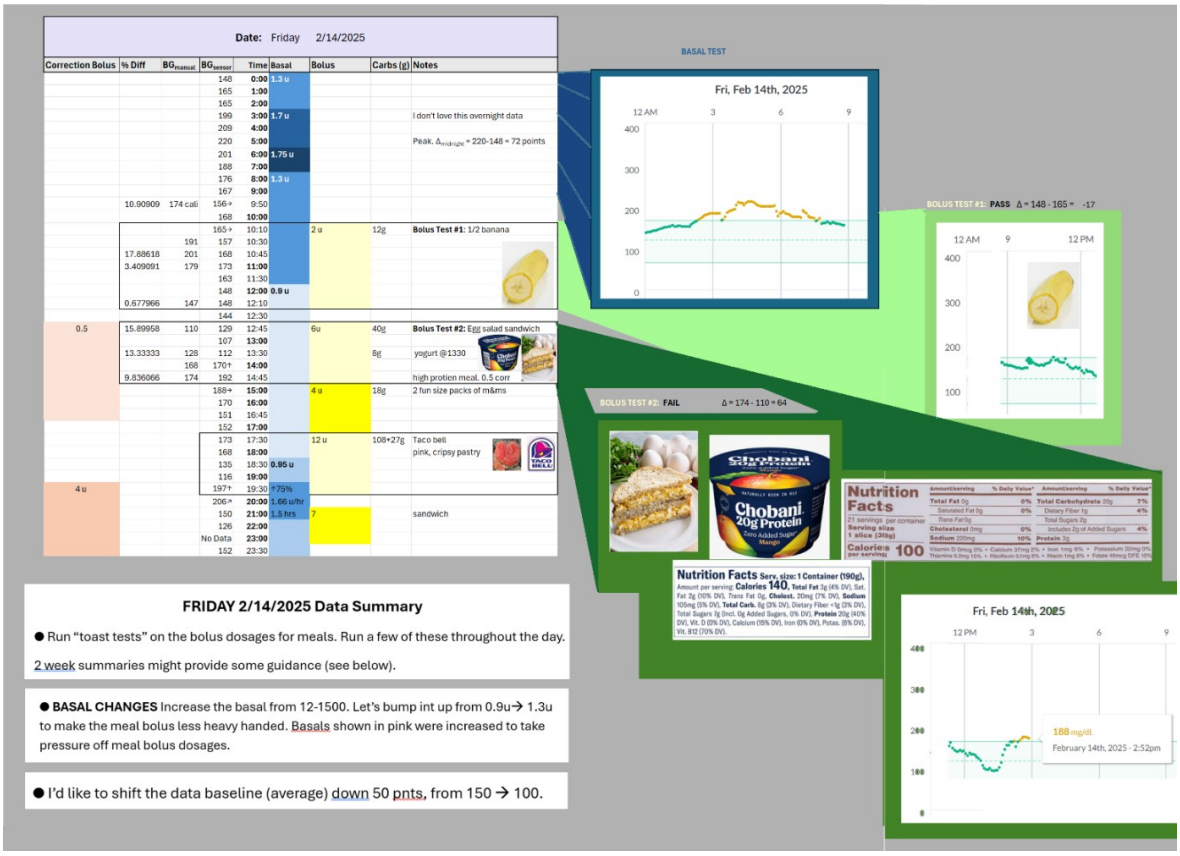
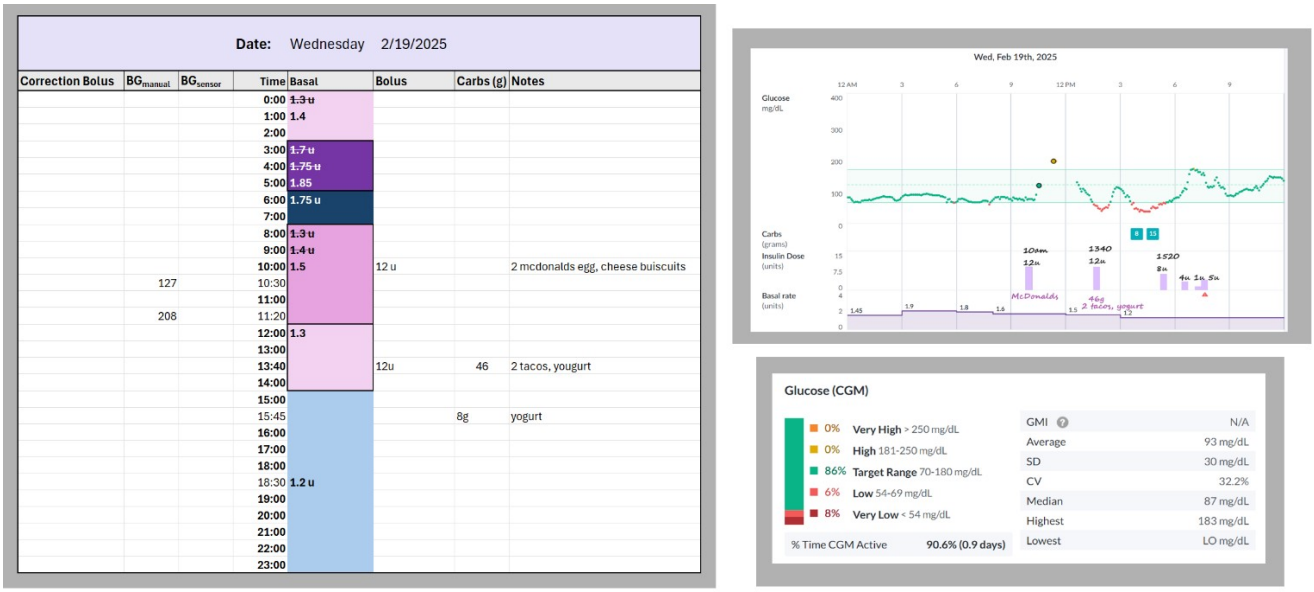

Date: Friday 2/14/2025
Correction Bolus
% Diff
BG manual
BG sensor
Time
Basal
Bolus
Carbs (g)
Notes
Bolus Test #1: 1/2 banana
Bolus Test #2: Egg salad sandwich
yogurt @1330
high protien meal. 0.5 corr
2 fun size packs of m&ms
Taco bell
pink, crispy pastry
sandwich
BASAL TEST
Fri, Feb 14th, 2025
BOLUS TEST #1: PASS Δ = 148 - 165 = -17
BOLUS TEST #2: FAIL Δ = 174 - 110 = 64
Chobani 20g Protein
Nutrition Facts
Nutrition Facts Serv. size: 1 Container (190g), Calories 140, Total Fat 2g, Cholest. 20mg, Sodium 105mg, Total Carb. 8g, Protein 20g
Fri, Feb 14th, 2025
188 mg/dl
February 14th, 2025 - 2:52pm
FRIDAY 2/14/2025 Data Summary
● Run "toast tests" on the bolus dosages for meals. Run a few of these throughout the day.
2 week summaries might provide some guidance (see below).
● BASAL CHANGES Increase the basal from 12-1500. Let's bump int up from 0.9u→ 1.3u to make the meal bolus less heavy handed. Basals shown in pink were increased to take pressure off meal bolus dosages.
● I'd like to shift the data baseline (average) down 50 pnts, from 150 → 100.

***Figure 21**. One Day of Data Collection & Analysis to Set My Insulin Dosages on February 14th, 2025*



Date: Wednesday 2/19/2025

Correction Bolus	BG_{manual}	BG_{sensor}	Time	Basal	Bolus	Carbs (g)	Notes
			0:00	~~1.3 u~~			
			1:00	1.4			
			2:00				
			3:00	~~1.7 u~~			
			4:00	~~1.75 u~~			
			5:00	1.85			
			6:00	1.75 u			
			7:00				
			8:00	1.3 u			
			9:00	1.4 u			
			10:00	1.5	12 u		2 mcdonalds egg, cheese buiscuits
	127		10:30				
			11:00				
	208		11:20				
			12:00	1.3			
			13:00				
			13:40		12u	46	2 tacos, yougurt
			14:00				
			15:00				
			15:45			8g	yogurt
			16:00				
			17:00				
			18:00				
			18:30	1.2 u			
			19:00				
			20:00				
			21:00				
			22:00				
			23:00				

***Figure 22**. Data from February 19th after changing some basal insulin dosages*

It’s through examples like this that we see how problems stemming from monopolization extend to more than just money. The problem isn't JUST the money. The larger problem is that healthcare money is all easy money. The problem with easy money is that nobody does any actual work. All the work that a failed industry gets paid to do, actually gets done by diabetic patients. It's as if, in 2025, Abbott and Epic want a pat on their head for incorporating blood sugar into their computer system. I've been collecting data via a sensor for ten or twenty years. I analyze that data. I adjust my insulin dosages. That’s why I am alive to write to you today.

The medical system uses threats and coercion to force my participation in services that they can bill for, but don’t even provide. They will revoke my access to insulin and other life sustaining medical equipment if I don’t participate. Forced participation enables providers to fail to uphold their Duty to Provide Care and takes away my rights as a patient either to consent to or refuse superfluous medical appointments.

I conduct countless communications each year to ensure that the medical system competently completes the paperwork required for me to obtain medications and medical devices. Figure 23 illustrates just how many communications, and in-person visits are required of me to maintain access to life preserving medications. It is completely unsustainable for working aged adults to unravel this many bureaucratic obstacles. There is no accountability because I bear the burden of their many failures. Jeffery

Pfeffer's 2020 study titled *Magnitude and Effects of "Sludge in Benefits Administration: How Health Insurance Hassles Burden Workers and Cost Employees*, estimates that, "…The economy loses $21.6 billion a year simply from the time employees spend on the phone with health insurance representatives." [38,39] Pfeffer conducted a study in conjunction with Gallup that revealed that as Americans, "We spend about 12 million hours a week calling our health insurance." [40,41] If I don't dedicate constant effort to them keeping their paperwork straight, then they fail in their Duty to Provide Care (maintain valid prescriptions) and the result is my death.

It begs the question, "Who in this arrangement requires constant accommodation due to disability? The patient or the medical system?" Why would I put the responsibility of advanced data analytics in the hands of an industry that can't even fulfill basic responsibilities like filling prescriptions? If you were an EMT who couldn't document care in a basic medical report, your competency at providing that care would certainly be called into question in a court of law. Yet players at the highest levels of medical licensure are paid and permitted to routinely and regularly fail to maintain their paperwork. The doctors have been castrated by the insurers and lack the professional agency to provide care. This may contribute to a lack of competence in the profession.

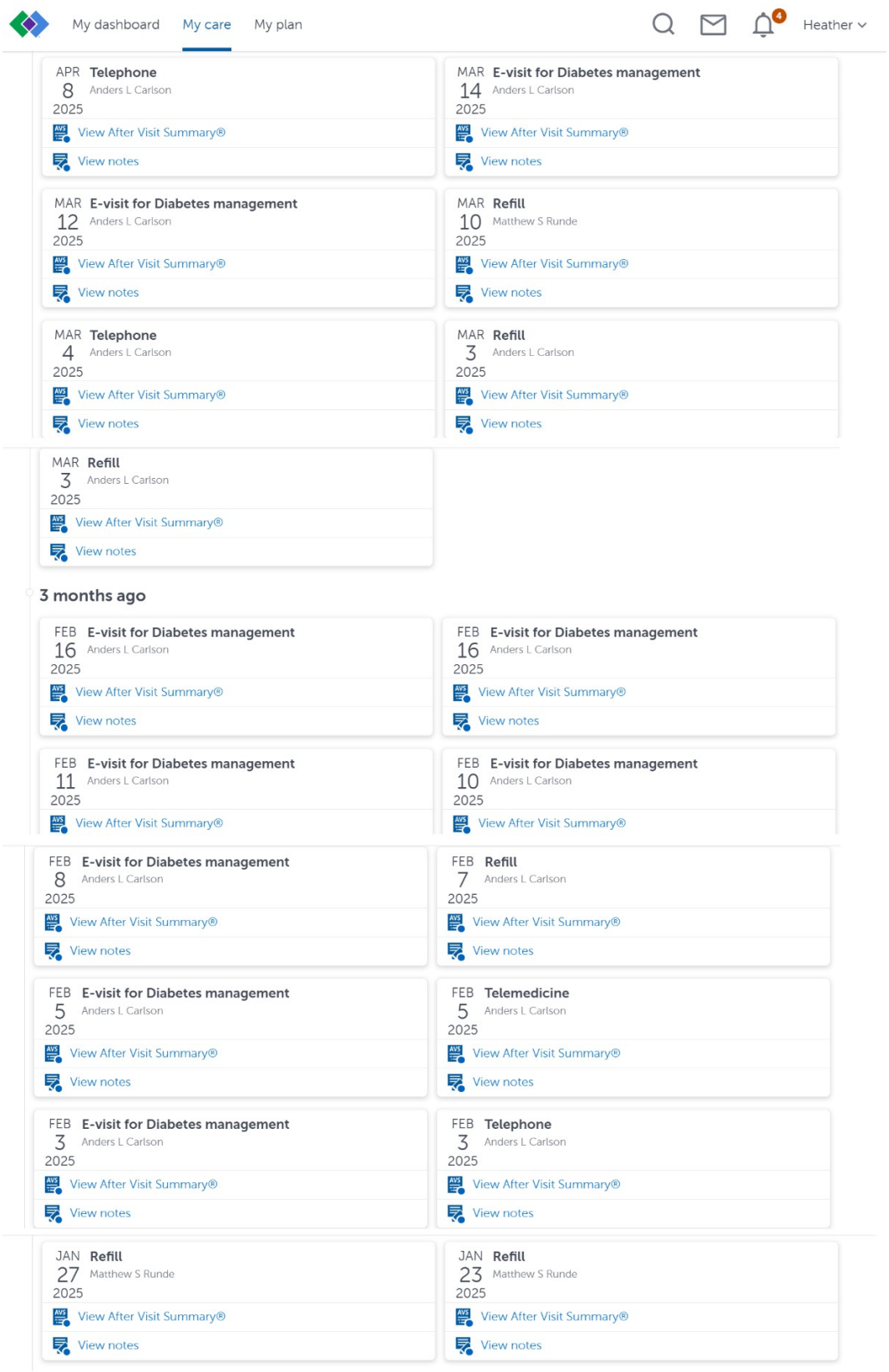

My dashboard
My care
My plan
Heather
APR 8 2025 Telephone Anders L Carlson
MAR 14 2025 E-visit for Diabetes management Anders L Carlson
MAR 12 2025 E-visit for Diabetes management Anders L Carlson
MAR 10 2025 Refill Matthew S Runde
MAR 4 2025 Telephone Anders L Carlson
MAR 3 2025 Refill Anders L Carlson
MAR 3 2025 Refill Anders L Carlson
View After Visit Summary®
View notes
3 months ago
FEB 16 2025 E-visit for Diabetes management Anders L Carlson
FEB 16 2025 E-visit for Diabetes management Anders L Carlson
FEB 11 2025 E-visit for Diabetes management Anders L Carlson
FEB 10 2025 E-visit for Diabetes management Anders L Carlson
FEB 8 2025 E-visit for Diabetes management Anders L Carlson
FEB 7 2025 Refill Anders L Carlson
FEB 5 2025 E-visit for Diabetes management Anders L Carlson
FEB 5 2025 Telemedicine Anders L Carlson
FEB 3 2025 E-visit for Diabetes management Anders L Carlson
FEB 3 2025 Telephone Anders L Carlson
JAN 27 2025 Refill Matthew S Runde
JAN 23 2025 Refill Matthew S Runde

***Figure 23**. Number of visits/communications required by me to keep my prescriptions valid*

Diabetic Technology Example #3. Software systems in practice

As systems age they become increasingly complex and less useful. High levels of complexity lead to system failures and systems that are difficult to change. This is more apparent in the case of healthcare system software as anywhere else. Healthcare is complex. Software is complex. The two intersect to form a special form of hell.

Professional software engineers must regularly refactor their code to “clean it up.” It’s necessary to do maintenance work that must occur because over time, the number of things that the software is required to do increases. The software might have been originally designed to do one thing, but over time it evolves to do something completely different. If you don’t clean it up, also known as software ‘refactoring,’ then it inevitably contains a bunch of meaningless garbage. Software bugs hide in that garbage and become increasingly difficult to find. Uncle Bob, author of Clean Code attempts to explain this inevitable deterioration is his video “Clean Code with Uncle Bob Episode 1.” [42]

I spoke with members of our state legislature about this problem over a five-year period when they attempted to revamp our aging Department of Motor Vehicle (DMV) software system called MNLARS. [43] The system had aged over time, was poorly maintained, became increasingly complex as new features were added, and eventually functioned so poorly that citizens and members of the legislature referred to it only as, “the goat rodeo.” It was consuming millions of dollars. Four large software companies were hired to fix it, but each in turn excused themselves from the contract. Elderly women where being arrested at gun point by police after their car titles didn’t transfer. MNLARS was randomly suspending my drivers license without notification due to software bugs resulting from a medical form submitted by the doctor to Driver and Vehicle Services (DVS) required for insulin dependent diabetics. Problems with this business process had occurred my entire driving life but problems had become increasingly problematic as both the software system and I aged. Eventually, there was no procedure possible that I could follow in order to guarantee myself a valid driver’s license. A Hennepin County prosecutor threatened to throw me in jail for driving with a suspended license and I spent the next five years working to fix MNLARS software bugs related to drivers licensing for diabetics because county jail is not a particularly safe place for type 1 diabetics and I needed to drive in order to maintain employment with a high enough salary to pay my health insurance premium ($400/month).

When I spoke to members of the state legislature, they told me that problems resulting from increasing system complexity were present in the law, as well as the software. They explained that the world changes around the law and if no one goes back to clean up old laws that no longer serve any value, then they become impediments to progress. The reason that both software developers and members of the legislature don't go back to old systems and "clean them up," is because that work is complicated and time consuming, particularly if you don't keep up on it regularly. Systems become like the house of an elderly grandmother who gradually loses her capacity to clean it. Eventually, it becomes unmanageable. This is the problem of healthcare software systems, and of healthcare more generally – system complexity and a lack of professional maintenance of those system. Systems must be engineered to allow for changes that are inevitably required over time. Systems that cannot accommodate change are not well engineered.

In this case, we had a public software system that inadvertently deteriorated over time. Maintenance may have been an afterthought or perhaps money and resources were not allocated or available. The result of that was that it cost exponentially more money to fix it than if it had been professionally maintained. Human lives were being ruined. Systems should never be allowed to function so poorly that they drain money exponentially out of the public coffers and prevent individuals from being contributing members of society. I was fortunate in this case that there were democratic mechanisms in place for me to address problems in the state's MNLARS computer system. Problems like this abound in healthcare computer systems and there are rarely mechanisms in place to address problems that actively restrict or remove an individual's rights from them. Software is the mechanism through which our individual rights are enforced or restricted today. The number of problems that stem from faulty software systems or that are intentionally engineered into complex systems is overwhelming. Let's briefly mention one example here.

The Change Healthcare ransomware attack was confirmed in January of this year to be the largest breach in U.S. history. [44] The system had been engineered such that Change Healthcare was a single point of failure for 190 million individuals receiving care in the U.S. [44] It impacted organizations throughout Minnesota, including our largest County hospital, Hennepin County Medical Center in the heart of downtown Minneapolis. UHG was tight lipped and revealed little to no information while our local IT teams worked to recover critical systems. During Congressional hearings, UHG promised to accommodate physician practices that were impacted. In practice, however,

complaints from physicians abounded, “UnitedHealth Group has adopted an aggressive approach to recover outstanding balances on loans issued to healthcare providers affected by the February 2024 ransomware attack…” [45] The American Medical Association (AMA) was forced to intervene. [46] Fairview Health Services, a Minneapolis system that operates ten hospitals filed suit over 7 million dollars in losses. (Figure 24) [48] Americans bristled at recollection of the 2008 financial crisis over the Senate Finance Committee statements issuing,

> **“…Dire warning about the consequences of “too big to fail” mega-corporations gobbling up larger and larger shares of the health care system. It is long past time to do a comprehensive scrub of UHG's anti-competitive practices, which likely prolonged the fallout from this hack. For example, Change Healthcare’s exclusive contracts prevented more than one third of providers from switching clearinghouses, even though Change’s systems were down for weeks.” [47]**

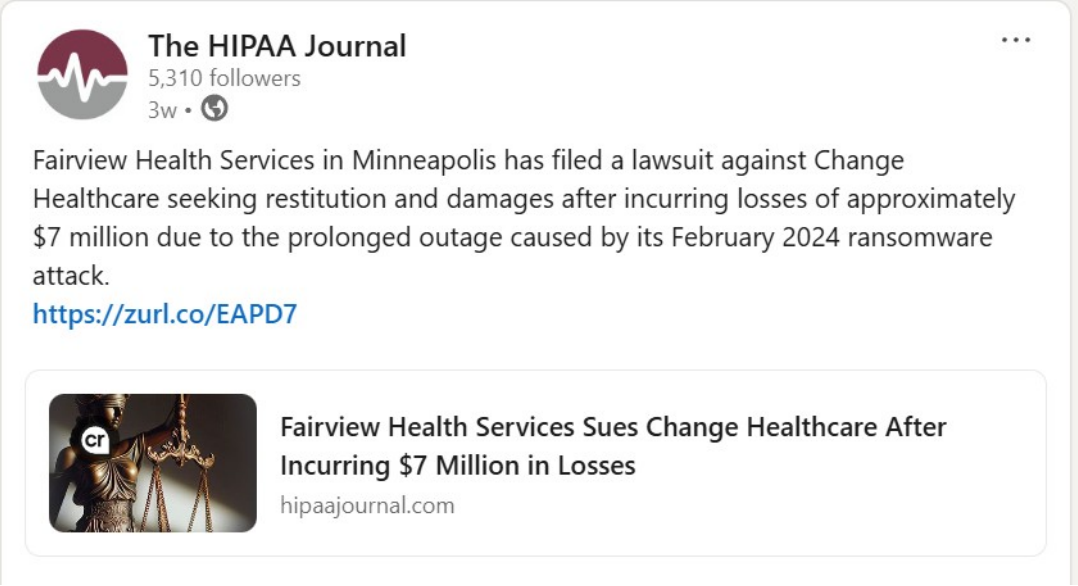

The HIPAA Journal
5,310 followers
3w •
Fairview Health Services in Minneapolis has filed a lawsuit against Change Healthcare seeking restitution and damages after incurring losses of approximately $7 million due to the prolonged outage caused by its February 2024 ransomware attack.
https://zurl.co/EAPD7
Fairview Health Services Sues Change Healthcare After Incurring $7 Million in Losses
hipaajournal.com

***Figure 24**. Fairview Health Services in Minneapolis files suit [48]*

Individual experience of physician experience and the impact on patients are available, including that of Christine Meyer of Pennsylvania, if you require deeper personal testimony from someone impacted. (Figure 25) [49] Optum is obstructing a doctor’s legal Duty to Provide Care, as a result of their own failures that resulting from their own intentional engineering of a single point of failure into the system. For that, patients pay the penalty because patients pay the penalty for every professional failure by the healthcare system.

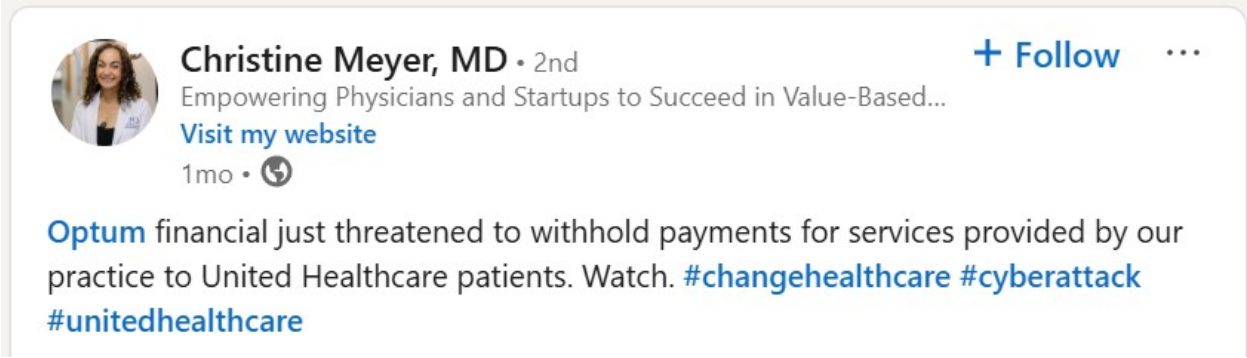

Christine Meyer, MD • 2nd
Empowering Physicians and Startups to Succeed in Value-Based...
Visit my website
1mo •
+ Follow
Optum financial just threatened to withhold payments for services provided by our practice to United Healthcare patients. Watch. #changehealthcare #cyberattack #unitedhealthcare

***Figure 25**. Christine Meyer - Physician impacted by the Change Breach [49]*

The Health of Labor Markets in Minneapolis

Undesirable impacts on labor markets, pay rates, and labor practices occur in Minneapolis because of healthcare and medical industry collusion. In Minneapolis, Optum (subsidiary of UHG) hires a team of 40 software engineers at one time, at a full-time rate of $2.50/hour. I was first contacted by email for this employment arrangement with Optum on December 7th, 2020, by Tanner Aho, a recruiter for TEKSystems (www.linkedin.com/in/tanneraho/). I spoke with Mr. Aho about the Optum position, and he said that Optum was unwilling to negotiate on salary because if they increased the salary for one person, they would be forced to increase it for all 40 people. He reassured me with a guarantee of *lots* of overtime as a mechanism for increasing the pay rate to something more desirable.

At that time, I wrote to the State of Minnesota Department of Labor to ask if $2.50/hour was a legal wage because, in all honesty, software engineering graduates receive so many employment arrangements with similarly low hourly rates that it seemed reasonable to check, especially given that it was coming from such a large employer in Minneapolis. The Minnesota Department of Labor replied that it *was* an illegal pay rate according to the *Minimum Wage for Technology Workers Act*, which requires a minimum pay rate, even if companies request that employees participate in company training or onboarding. They, however, stated that they had no enforcement capability unless engineers accepted employment, worked for some period, and then filed a formal labor complaint. When I spoke to them recently, they didn't know of any minimum wage laws tied to specific industries, so perhaps I received misinformation in 2020, or perhaps the laws have changed. But

however you slice it, I don’t believe $2.50/hour is a legal wage in this circumstance.

I was again contacted regarding this employment arrangement on January 3, 2022, by Tyler Godes. (Figure 26) After being approached a few times, I wrote to the Minnesota attorney General and received the reply and communication receipt shown in figures 27 and 28.

This lack of enforcement and widespread proclivity for paying wages that are not in accordance with the law, by one of the largest companies in town, has an ill effect on the Minneapolis labor market. 12-week sprints allow Optum to complete a significant amount of software development work, nearly for free, without threat of any repercussions. Optum does not comply with state minimum wage standards. The University of Saint Thomas is one of two universities that produces software engineers in our local market. Last May, they graduated 22 students with an MS in Software Engineering (data provided via email correspondence with Melissa Howland, of the University, on 5/8/2025). Optum attempts to hire teams that are twice that number, which I argue impacts the profession at large and provides incentive for other companies to pursue the same practices, driving wages lower for the entire profession in my geographic area. Yet, it represents only one additional example of the many ways large PBMs engage in market fixing as a long-term strategy that is destructive to the health of markets more broadly. Strategies like this require significant taxpayer money, in addition to significant time and effort by public officials to combat.

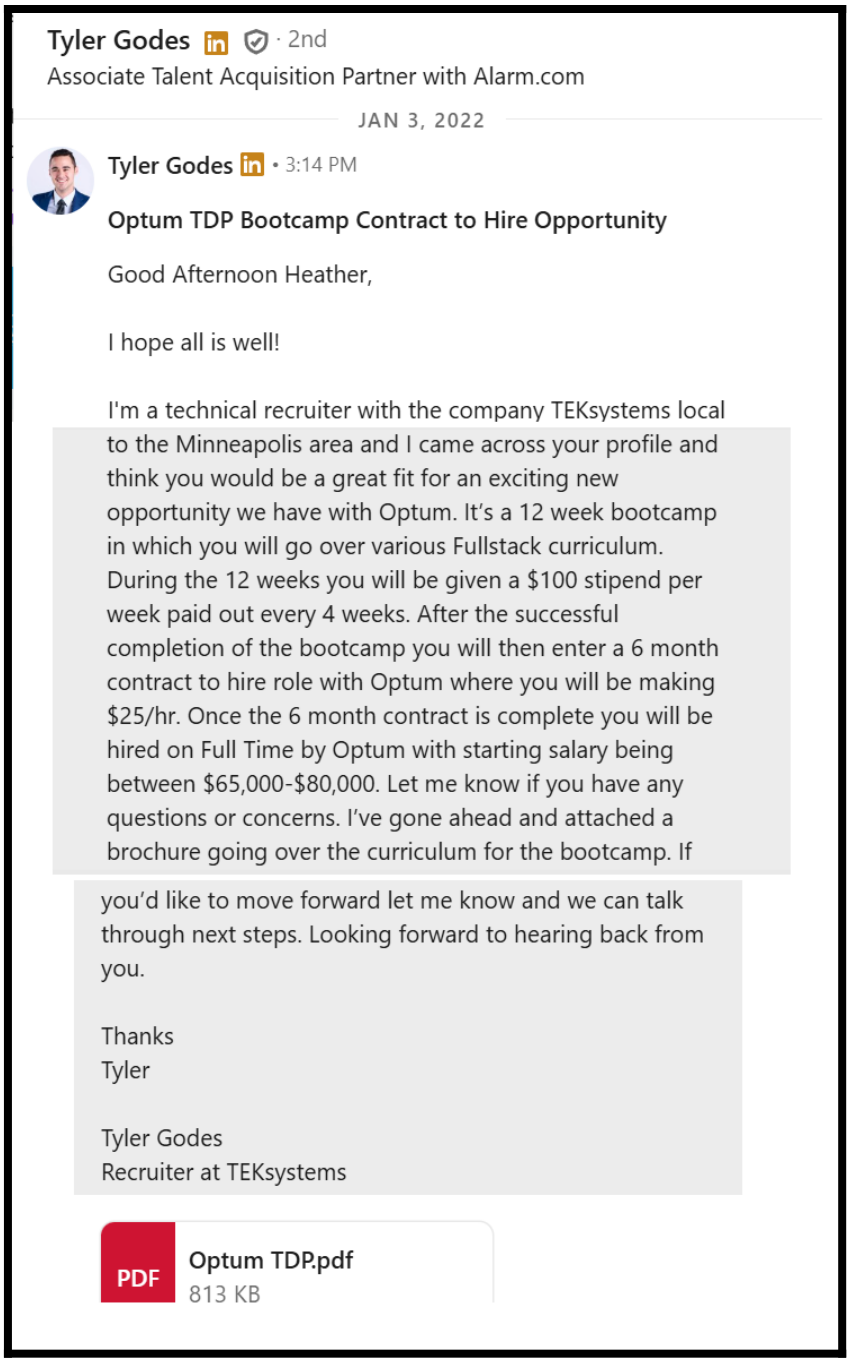

Tyler Godes · 2nd
Associate Talent Acquisition Partner with Alarm.com
JAN 3, 2022
Tyler Godes • 3:14 PM
Optum TDP Bootcamp Contract to Hire Opportunity
Good Afternoon Heather,
I hope all is well!
I'm a technical recruiter with the company TEKsystems local to the Minneapolis area and I came across your profile and think you would be a great fit for an exciting new opportunity we have with Optum. It's a 12 week bootcamp in which you will go over various Fullstack curriculum. During the 12 weeks you will be given a $100 stipend per week paid out every 4 weeks. After the successful completion of the bootcamp you will then enter a 6 month contract to hire role with Optum where you will be making $25/hr. Once the 6 month contract is complete you will be hired on Full Time by Optum with starting salary being between $65,000-$80,000. Let me know if you have any questions or concerns. I've gone ahead and attached a brochure going over the curriculum for the bootcamp. If you'd like to move forward let me know and we can talk through next steps. Looking forward to hearing back from you.
Thanks
Tyler
Tyler Godes
Recruiter at TEKsystems
PDF
Optum TDP.pdf
813 KB

Figure 26. *Optum recruits 40 software engineers in Minneapolis at a time, at a pay rate of $2.50/hour*

Office of the Minnesota Attorney General<AG.Replies@ag.state.mn.us>

To: You

Thu 9/21/2023 11:16 AM

1c_5395732_TNG - EMAIL.pdf
185 KB

Please find the attached correspondence from the Minnesota Attorney General's Office.

If you are sending a response via email or fax, please INCLUDE YOUR FILE NUMBER: TNG/2023/5395732/C in the subject line of your response.

Thank you

Office of the Minnesota Attorney General Disclaimer: This e-mail is intended

***Figure 27**. Communication receipt*

The Office of
Minnesota Attorney General Keith Ellison
helping people afford their lives and live with dignity, safety, and respect • www.ag.state.mn.us

September 21, 2023

Ms. Heather Mortensen
PO Box 964
Anoka, MN 55303
Via Email: mort0048ii@outlook.com

Dear Ms. Mortensen:

I thank you for your correspondence, received on September 16, 2023, regarding concerns about an employment inquiry you received from an employment recruiter at TEKsystems on behalf of Optum.

While I cannot give you legal advice, I can tell you the following, which I hope will be helpful:

You indicate that you contacted the Minnesota Department of Labor and Industry ("DLI") with your concerns. As you likely know, DLI is the state agency with the authority to investigate and take enforcement action against employers that violate Minnesota's wage and hour laws. Accordingly, you may wish to follow up with DLI's Labor Standards Division as follows:

Labor Standards Division
Minnesota Department of Labor and Industry
443 Lafayette Road North
St. Paul, MN 55155
Phone: (651) 284-5075
Toll-free: 1 (800) 342-5354
Email: dli.laborstandards@state.mn.us
Website: www.dli.state.mn.us

I thank you again for your correspondence.

Respectfully,

Taylor Griffin

TAYLOR GRIFFIN
Senior Correspondence Specialist

|#5594907-v1

445 Minnesota Street, Suite 1400, St. Paul, MN 55101-2131
Office: (651) 296-3353 • Toll Free: (800) 657-3787 • Minnesota Relay: (800) 627-3529
An Equal Opportunity Employer Who Values Diversity

***Figure 28**. Response to labor concerns*

Market Consolidation in the form of Pharmacy Closures

Imagine the market pressures on independent, family run pharmacies if even Walgreens can't stay afloat unless purchased by private equity. [69] There is nowhere left for free markets to hide from industry consolidation. It impacts patients. Kickbacks and Safe Harbor laws enable bad behavior to flourish without restraint. [70,71]

Patient Experience #4. Lost access to insulin pump for 5 days in 2025

Figure 29 shows me losing access to my insulin pump, most recently for 5 days in January, despite dedicating around 20 hours per week, for three weeks, to filling the script. I worry that unanticipated loss of access to medical equipment and medications for diabetics represents not only risk to the patient, but some risk to public safety.

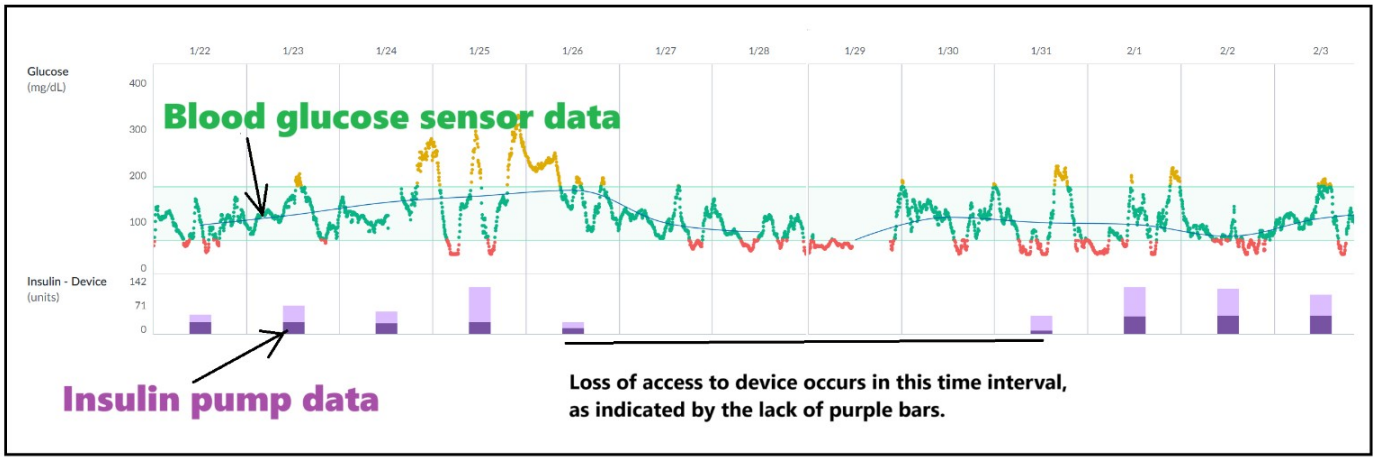


***Figure 29**. Medical records from a software program called Glooko show loss of access to my insulin pump for four full days and 2 partial days (approximately 5 days) between Jan 26th and Jan 31st, 2025*

A helpful Walgreens tech at a store in Andover, Minnesota suggested that we locate pharmacies with the device in stock and I attempted to purchase pods at those locations directly. There were two pharmacies with the devices in stock – Brooklyn Park and South Saint Paul. I went to Brooklyn Center first. The staff there stated that they would not be able to fill any prescriptions that day due to staff shortages. This is a strange new market failure that has recently popped up. Both Walgreens locations in Anoka have started either limited hours or randomly closing their doors during periods of understaffing. (Please see figure 30) I instead drove to the Walgreens location on Robert Street in South Saint Paul, where I successfully filled the prescription for pods and was able to resume insulin delivery via Dash pods on January 31st.

Pharmacy hours
Pharmacy temporarily
CLOSED
Due to unforeseen circumstances, this pharmacy has temporarily stopped providing the following services:
1. Prescription Dispensing
2. Medication Counseling
3. Immunization and Diagnostic Testing Services (COVID-19 & flu testing)
Anticipated reopening date and time:
2/5/2025 9:00 am
Nearest Walgreens pharmacy:
11401 Marketplace Dr N Champlin, MN 55316
Nearest Walgreens pharmacy open 24 hours or extended hours:
10686 University Ave. NW Coon Rapids, MN 55448
For more locations, visit our app or Walgreens.com.
We apologize for any inconvenience.
To reschedule your vaccine appointment, scan here:
To reschedule your testing appointment, scan here:
Please talk to our pharmacy team members if you have any questions.

***Figure 30**. Photo from Walgreens on Main Street in Anoka, Minnesota when it randomly shut its doors due to understaffing on Tuesday February 4th, 2025*

Summary

If the states or the federal legislature could manage the complex influence of Pharmacy Benefit Mangers (PBM) like UHG on the marketplace, then they would have done it by now. The state of Minnesota has been working on medical monopoly busting since 2018. They were the first state in the nation to pass legislation requiring PBM licensure and data submission. There are currently 41 state attorney generals asking for action on PBM reform. [14] Highly resilient, bipartisan legislation supported by a wide variety of stakeholders, such as patients, providers, and independent pharmacists has moved up to the federal agencies and legislators from most state governments. Large employers will be forced to manage PBM liability or face liability. [66] However, the problem of monopolization in healthcare is a complicated twisted web woven over decades. Governmental expertise and experience on the topic of antitrust resides in our federal agencies. The problems of people are practical problems, not partisan ones.

Without good data, you can't make good policy. Independent pharmacists are the small business and the 'numbers guys.' Publications like those of Antonio Ciaccia, *Money from Sick People* make great effort to explain their analysis, which can be technical in nature and confusing for members of the legislature. [67, 68] Pharmacists for Truth and Transparency has a podcast, and they are already willing to talk. Speaking with more stakeholders creates better policy – that may require conversations with doctors, pharmacists, and patients.

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